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Abstract

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Background: Men who have sex with men (MSM) experience significant inequalities in health and well-being. They are the group in the UK at the highest risk of acquiring a human immunodeficiency virus (HIV) infection. Guidance relating to both HIV infection prevention, in general, and individual-level behaviour change interventions, in particular, is very limited.

Objectives: To conduct an evidence synthesis of the clinical effectiveness of behaviour change interventions to reduce risky sexual behaviour among MSM after a negative HIV infection test. To identify effective components within interventions in reducing HIV risk-related behaviours and develop a candidate intervention. To host expert events addressing the implementation and optimisation of a candidate intervention.

Data sources: All major electronic databases (British Education Index, BioMed Central, Cumulative Index to Nursing and Allied Health Literature, EMBASE, Educational Resource Index and Abstracts, Health and Medical Complete, MEDLINE, PsycARTICLES, PsycINFO, PubMed and Social Science Citation Index) were searched between January 2000 and December 2014.

Review methods: A systematic review of the clinical effectiveness of individual behaviour change interventions was conducted. Interventions were examined using the behaviour change technique (BCT) taxonomy, theory coding assessment, mode of delivery and proximity to HIV infection testing. Data were summarised in narrative review and, when appropriate, meta-analysis was carried out. Supplemental analyses for the development of the candidate intervention focused on post hoc realist review method, the assessment of the sequential delivery and content of intervention components, and the social and

historical context of primary studies. Expert panels reviewed the candidate intervention for issues of implementation and optimisation.

Results: Overall, trials included in this review ($n = 10$) demonstrated that individual-level behaviour change interventions are effective in reducing key HIV infection risk-related behaviours. However, there was considerable clinical and methodological heterogeneity among the trials. Exploratory meta-analysis showed a statistically significant reduction in behaviours associated with high risk of HIV transmission (risk ratio 0.75, 95% confidence interval 0.62 to 0.91). Additional stratified analyses suggested that effectiveness may be enhanced through face-to-face contact immediately after testing, and that theory-based content and BCTs drawn from 'goals and planning' and 'identity' groups are important. All evidence collated in the review was synthesised to develop a candidate intervention. Experts highlighted overall acceptability of the intervention and outlined key ways that the candidate intervention could be optimised to enhance UK implementation.

Limitations: There was a limited number of primary studies. All were from outside the UK and were subject to considerable clinical, methodological and statistical heterogeneity. The findings of the meta-analysis must therefore be treated with caution. The lack of detailed intervention manuals limited the assessment of intervention content, delivery and fidelity.

Conclusions: Evidence regarding the effectiveness of behaviour change interventions suggests that they are effective in changing behaviour associated with HIV transmission. Exploratory stratified meta-analyses suggested that interventions should be delivered face to face and immediately after testing. There are uncertainties around the generalisability of these findings to the UK setting. However, UK experts found the intervention acceptable and provided ways of optimising the candidate intervention.

Future work: There is a need for well-designed, UK-based trials of individual behaviour change interventions that clearly articulate intervention content and demonstrate intervention fidelity.

Study registration: The study is registered as PROSPERO CRD42014009500.

Funding: The National Institute for Health Research Health Technology Assessment programme.

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List of abbreviations

AIDS	acquired immune deficiency syndrome
BCT	behaviour change technique
CBT	cognitive–behavioural therapy
CDC	Centers for Disease Control and Prevention
CI	confidence interval
C-M-O	context, mechanism and outcome
DTS	dual theoretical synergy
GUM	genitourinary medicine
HIV	human immunodeficiency virus
MET	motivational enhancement therapy
MI	motivational interviewing
MSM	men who have sex with men
NICE	National Institute for Health and Care Excellence
NPT	normalisation process theory
PAG	project advisory group
PCC	personal cognitive counselling
PPI	public and patient involvement
PrEP	pre-exposure prophylaxis
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	randomised controlled trial
STI	sexually transmitted infection
TasP	treatment as prevention
TDF	theoretical domains framework
UAI	unprotected anal intercourse

Plain English summary

The problem

There is a lack of guidance regarding human immunodeficiency virus (HIV) infection prevention in the UK. When guidance does exist, it is quite general. It does not provide detail about particular interventions that can change risky sexual behaviour among men who have sex with men (MSM).

How we addressed the problem

We looked at published scientific studies that described interventions for MSM and were designed to change sexual risk-related behaviour (e.g. increase condom use) after receiving a negative result from a HIV infection test. We wanted to know if these behaviour change interventions actually worked. We also wanted to know how they worked and why.

What we found

We found that these interventions improved sexual risk-related behaviour. It was more difficult to understand how and why they worked, but it was possible to set out the key components of these interventions. These key components included delivering interventions face to face immediately after HIV infection testing, supporting men in thinking through the consequences of their behaviour and identifying their future sexual health goals and encouraging them to identify solutions to the problems they perceive in realising these goals.

Is it possible to implement such an intervention in the UK?

We consulted experts who work in sexual health in the UK. Overall, they thought that the intervention we developed was acceptable and that it could help them. Although the findings of the report are very useful, they are based on rather old studies that were conducted outside the UK. We believe that UK research is needed to make sure that behaviour change interventions are as effective and relevant as they can be.

Scientific summary

Background

Men who have sex with men (MSM) experience significant inequalities in health and well-being. They are the group in the UK that is at the highest risk of acquiring a human immunodeficiency virus (HIV) infection. Guidance relating to both HIV infection prevention, in general, and individual-level behaviour change interventions, in particular, is very limited.

Objectives

To conduct an evidence synthesis of the clinical effectiveness of behavioural change interventions to reduce risky sexual behaviour among MSM after a negative HIV infection test. To identify the components within interventions that are most effective in reducing HIV risk-related behaviours and to develop a candidate intervention. To host expert events addressing the implementation and optimisation of a candidate intervention.

Data sources

Electronic databases (British Education Index, BioMed Central, Cumulative Index to Nursing and Allied Health Literature, EMBASE, Educational Resource Index and Abstracts, Health and Medical Complete, MEDLINE, PsycARTICLES, PsycINFO, PubMed and Social Science Citation Index) were searched between January 2000 and December 2014.

Study selection

Studies were included if the majority of men (> 66%) were HIV negative, verified by confirmed status, self-report status or through testing as part of the study procedures. Studies were excluded if they focused exclusively on commercial sex workers, people who are transgender, victims of sexual or domestic abuse or violence, intravenous drug users, and those in prison, psychiatric facilities or nursing homes or individuals with no fixed address. All individual-level behavioural change interventions designed to promote HIV infection risk reduction were included as long as they were brief (short duration and between one and five sessions). Relevant comparators were usual care or minimal intervention.

Data extraction

Data relating to study design, quality, sample characteristics, interventions and comparators, and primary and secondary outcomes were extracted using a standard pro forma. Study quality was assessed according to the Cochrane risk-of-bias assessment tool for randomised controlled trials. Data were extracted from the studies by one reviewer and checked by a second. Any disagreements were resolved through consensus or, if necessary, by referral to a third reviewer. Intervention content was assessed using the behaviour change technique (BCT) taxonomy version 1, the theory coding scheme, and assessment of intervention fidelity by using the Treatment Fidelity Checklist. Intervention content was reviewed by two independent reviewers who coded BCTs. Disagreements and additional BCTs identified were subsequently discussed. Where agreement could not be reached, a third reviewer resolved the discrepancies between the first two reviewers. Data utilised in the post hoc realist synthesis were extracted by a single reviewer and checked by a second.

Data regarding the sequencing of intervention components, and the historical and social context of primary studies, were extracted by one reviewer.

Data synthesis

All data were tabulated, discussed in a narrative review and, where appropriate, subjected to pairwise meta-analysis. Supplemental data synthesis for the development of the candidate intervention focused on post hoc realist review methods. These re-examine primary studies and associated tabulated data through several iterative stages [familiarisation, individual context, mechanism and outcome (C-M-O) configurations, patterns across C-M-O configurations, the development of general statements and the development of explanatory theories], which are in turn used to formulate hypotheses in a final refined framework. Equally, data were synthesised across the assessment of the sequential delivery and content of intervention components, and the social and historical context of primary studies. A final process of metasynthesis examined patterns in evidence provided by the narrative review, meta-analyses, the realist review and the sequential content of interventions to develop a detailed candidate intervention.

Results

Overall, the trials included in this review ($n = 10$) reported positive findings and suggest that individual-level behavioural change interventions are effective in reducing HIV risk-related behaviour in HIV-negative MSM. Overall, there is a statistically significant reduction in behaviours most associated with risk of HIV transmission (risk ratio 0.75, 95% confidence interval 0.62 to 0.91), although there is considerable statistical and methodological heterogeneity in primary studies ($I^2 = 57\%$; $\tau^2 = 0.04$). Exploratory stratified meta-analyses suggested that effectiveness may be enhanced through face-to-face contact immediately after testing, theory-based content, and BCTs drawn from 'goals and planning' and 'identity' groups. Realist review methods highlighted additional aspects of primary studies that potentially enhance intervention effectiveness; these included a focus on the affective dimensions of intervention receipt and an acknowledgement of the complex skills needed by interventionists. Examination of the sequential content of interventions highlighted the potential importance that they have multiple components delivered with increasing complexity and often focusing on a single developmental, or narrative, trajectory, beginning with the personal exploration of risk-related behaviour and ending with the client setting goals or agreeing an action plan for future behaviour. Metasynthesis of these data provided sufficient detail to develop a candidate intervention.

The candidate intervention

Delivery

The results suggested that the candidate intervention should be delivered immediately after testing and should be delivered face to face. Interventions should be delivered by people with skilled facilitation techniques.

Content and purpose

The intervention should be non-judgemental, and include a reduction in negative effect and an increase in positive effect. Interventions should focus on high-risk men and, if possible, demonstrate some novelty, or capture contemporary issues affecting gay men and their sexual cultures. Interventions should be sensitive to issues of identity and contain a clear focus on the gay community. The intervention should deliver a demonstrable sense of cultural competency. Moreover, interventions should be multicomponent and be composed of sequential elements: they should begin with a risk assessment, include a normative peer reference point and the use of discrete tools, and end with a future-facing element.

The candidate intervention should be personalised and address the intrasubjective (i.e. include elements that encourage clients to consider their own thinking as part of how they should change their behaviour).

It should focus on encouraging a sense of individual responsibility but be mindful of issues concerning capacity, for example paying particular attention to issues of health and digital literacy.

In terms of the specific content the candidate intervention should utilise theory-congruent BCTs if possible and be based on the following: 'goals and planning', 'identity', 'social support' and 'comparative outcomes'. It should utilise the following specific BCTs: 'pros and cons', 'goal-setting' 'social support (emotional)', 'framing and reframing,' 'incompatible beliefs', 'social support (unspecified)' and 'information about health consequences'.

The candidate intervention was further optimised through expert events that highlighted the overall acceptability of the candidate intervention and its fit with existing service provision in the UK. They recommended that it was important to acknowledge the role of institutional support, clearly defined intervention content and details of intervention delivery, provide training to ensure intervention fidelity, consider clinical rather than community settings, and identify the financial barriers to implementing the intervention.

Limitations

There were a limited number of primary studies. Among these primary studies there was considerable methodological and statistical heterogeneity. The lack of detailed intervention manuals limited the assessment of content and delivery.

Conclusions

The evidence regarding the effectiveness of behaviour change interventions suggests they are effective in reducing those behaviours associated with the highest risk of HIV transmission. Effectiveness is likely to be enhanced through face-to-face delivery and delivery associated with HIV infection testing. There are uncertainties around the generalisability of these findings to the UK setting, however, experts from the UK found the candidate intervention acceptable and implementable.

Future work

There is a need for well-designed, UK-based trials of individual behaviour change interventions among MSM. These should clearly articulate intervention content in terms of the granularity of BCTs and the sequential ordering of intervention components. Adequate mixed-methods process evaluation should address and validate hypothesised mechanisms of behaviour change and methods should be adopted that can rigorously demonstrate intervention fidelity.

Study registration

The study is registered as PROSPERO CRD42014009500.

Funding

The National Institute for Health Research Health Technology Assessment programme.

Chapter 1 Background and rationale

The health problem

Men who have sex with men (MSM) experience significant inequalities in health and well-being, and a disproportionate burden of ill health in relation to sexual health, mental health and substance use.[1] MSM is the group at highest risk of acquiring a human immunodeficiency virus (HIV) infection in the UK. In 2013, it represented 54% of all new diagnoses in the UK. Data from Scotland concerning 2005–9 showed a relatively stable incidence rate among MSM of around 15.3/1000 person-years. The most recent available UK data[1] show that, across the UK, 3250 new HIV diagnoses in MSM were reported in 2013. In terms of diagnosis rates, given that there are an estimated 43,500 MSM living with HIV in the UK, this is equivalent to 59 out of 1000 MSM aged 15–59 years. Moreover, an estimated one in five, or 7200, HIV-positive MSM in the UK remain undiagnosed[2] and approximately 1000 are diagnosed late each year (i.e. within 3 months of diagnosis they report a CD4 count of < 350 cells/mm^2).[1] Delayed diagnosis is associated with poorer health outcomes[3,4] and treatment response, increased mortality and health-care costs and increased levels of onward transmission. Given that men living with HIV who are taking effective antiretroviral therapy are highly unlikely to transmit HIV,[5] it is clear that undiagnosed infection, particularly primary infection (when individuals are extremely infectious), is responsible for most new infections.[6] Mathematical modelling suggests that increased testing, linkage to care and early treatment could reduce HIV infection incidence in MSM.[7] Furthermore, currently we know that most undiagnosed infections in the UK have been acquired recently.[1] Indeed, the proportion of new diagnoses associated with recent transmission increased in some parts of the UK between 2011 and 2013, from 23% to 30%. Therefore, there is evidence that ongoing new infections are a particular challenge for HIV infection prevention. HIV infection testing rates among MSM overall have increased[8] and 83% of sexually transmitted infection (STI) clinics report HIV infection testing coverage of at least 80% among MSM patients.[1] Increasing the frequency of testing to every 3 months for men at increased risk of HIV infection is recommended in the UK and other national guidelines[9,10] and is highly likely to be cost-effective at the incidence observed in UK MSM genitourinary medicine (GUM) clinic attendees.[11] Together these factors highlight the considerable opportunities for prevention of onwards transmission among MSM following HIV infection testing.

In the last few years there have been major changes in HIV infection prevention in the UK. These changes are complex. They represent the interplay of a range of issues including factors relating to the diversification of HIV infection prevention initiatives and concomitant biomedical and wider cultural changes. In terms of cultural changes to HIV infection prevention, innovations within social media (particularly geospatial social media network applications or 'app'-based platforms) have led to changes in patterns of sexual mixing between men. Social media platforms, like the internet platforms that preceded them, facilitate seroadaptive approaches to HIV infection prevention, reducing the risk of onward transmission (wherein risk of onward transmission of HIV is minimised by HIV status disclosure and subsequent condomless sex occurring between men of the same HIV status). However, sexual mixing facilitated by online communication is also responsible for increases in a range of other negative health outcomes among MSM. For presumed HIV-negative men, the effectiveness of seroadaptive behaviours is dependent on accurate assessment of their own and their partners' HIV status, limited by the high rate of seroconversion and high infectivity of undiagnosed newly positive men. For men living with HIV there is a rising incidence of a number of STIs, with a significant rise in the ratio of bacterial STIs observed in HIV-positive compared with HIV-negative men in recent years.[12] Certain STIs, including hepatitis C virus and lymphogranuloma venereum, are seen predominantly, but not exclusively, in MSM living with HIV,[13,14] and recent outbreaks of syphilis and enteric infections, including shigellosis,[15,16] across the UK are associated both with high proportions of HIV-positive MSM, sexualised drug use and the use of geospatial social networking apps.[17] These observations suggest a complex picture of dense sexual networks of HIV-positive MSM[12] and populations of men at high risk, who are currently HIV uninfected or undiagnosed.[18] Social media applications are also implicated within the rise of what has been

described as 'chemsex', in which recreational drugs are taken in an explicitly sexual context[19] and the easy, or 'instant', organisation of sex parties. There is emerging evidence that sex parties organised online facilitate the transmission of a number of STIs, including HIV. In the light of these recent and significant changes to the sociocultural contexts of sex between men, particularly the increases in condomless sex,[20] HIV infection prevention and concomitant risk-reducing interventions must address the shifting and inter-related psychosocial and sociocultural contexts of HIV transmission.

Biomedical changes to HIV infection prevention, some of which are underpinning recent cultural changes, have recently been used effectively to reduce the chance of HIV transmission. These biomedical approaches can be thought of in two distinct ways: treatment as prevention (TasP), in which antiretroviral drugs, when taken effectively by individuals living with HIV, reduce transmission by reduction in both individual and population viral loads;[21] and pre-exposure prophylaxis (PrEP), in which HIV-negative men take antiretroviral drugs to reduce the chance of exposure to HIV resulting in established infection. In these ways, antiretroviral drugs can be used alongside condomless sex to reduce the risks of HIV transmission. Recent UK[22] and French[23] trials have demonstrated that PrEP can reduce HIV transmission among MSM by up to 86% and also serve to illustrate the very high incidence of HIV infection in MSM eligible for the trial [9.1% per annum in the Pre-exposure Option for reducing HIV in the UK: immediate or Deferred (PROUD) study], who represent a sizeable minority of MSM attending GUM clinics. Moreover, recent population surveys among MSM suggest growing PrEP awareness and widespread acceptability among those men who would benefit most from using them.[21] Future behaviour change interventions must incorporate and reflect these biomedical developments within HIV infection prevention. It seems likely that the most effective HIV infection prevention interventions will combine mechanisms of action that encompass a combination of biomedical, psychological and social approaches.

Alongside these pharmaceutical interventions, and of particular relevance to the current report, there have also been significant changes in access to, and the monitoring of, the fundamental technologies associated with HIV infection testing (e.g. self-sampling and self-testing). The range of contexts in which testing can take place has changed profoundly since the widespread availability of antiretroviral drug therapy. HIV infection testing continues to take place within traditional clinical settings (e.g. GUM clinics), yet following guidance from the National Institute for Health and Care Excellence (NICE) in 2011,[24] provision is also recommended in a range of community settings. With changes in legislation in April 2015, instant-result home HIV infection testing is now possible, with tests delivered via the internet or purchased over the counter and results available within a few minutes to the person testing.[25] Equally, HIV self-sampling has become relatively commonplace and has high acceptability; samples are self-collected and returned for laboratory-based testing, with the results given to individuals at a later date.[26,27] Test results are often delivered electronically using mobile phone technology for non-reactive results and recalling those people with reactive test results for further testing.

Finally, in terms of key changes in the infection prevention landscape, the commissioning and implementation of HIV infection prevention services has also changed in key ways. In terms of the very ethos of HIV infection prevention, there has been a widespread recognition of the wider psychosocial and sociocultural determinants of HIV infection risk and sexual ill health among MSM in the UK.[28–30] This acknowledgement of the multiple and distal determinants of HIV risk, and its syndemic qualities, again merits a pluralistic approach to HIV infection prevention. Equally, the way HIV infection prevention is commissioned across the UK has changed, with a diversification of approach between the nation states. In Scotland, for example, HIV infection prevention is commissioned within the NHS at the local health board level, but in England HIV infection prevention is commissioned both by local authorities and at a national level by Public Health England (see *Significance to the NHS*).

In summary, HIV transmission among MSM in the UK remains an ongoing problem, with significant implications for health and social care. Our understanding of HIV transmission risk itself has changed fundamentally, from simple concepts such as, in the past, condom use per se to more contemporary understandings that necessitate simultaneous consideration of condoms, HIV status, use of antiretroviral

drugs, viral loads, sexual position, disclosure, the social context of sex and patterns of sexual mixing (e.g. social media and sex parties). Equally, there has been a growing recognition of the complexity of factors that are associated with HIV transmission and the concomitant need for HIV infection prevention interventions to address this complexity (so focusing on the distal as well as proximal determinants of HIV transmission). It is vital that interventions are developed which reduce HIV transmission and take account of the wider health inequalities associated with those vulnerable to HIV infection. Innovations in biomedical approaches to HIV infection prevention (such as TasP or PrEP) demand further interprofessional and interdisciplinary understanding in the context of the psychosocial and sociocultural factors that determine their effective use. There are clear pharmacological mechanisms of action implicated with the use of antiretroviral drugs for HIV infection prevention (in PrEP and TasP it is the action of drugs on viral replication). However, it is psychological, social and cultural factors that shape decisions to initiate, maintain and terminate the adoption of these particular prevention approaches. Their effective use demands a concomitant investigation of the psychosocial determinants of their use, and the provision of psychosocial interventions, to maximise the opportunities such approaches will bring.

Significance to the NHS

There is limited information concerning lifetime costs of HIV infection and wider considerations of the economic and social burden of HIV infection. However, recent estimates of health-care costs associated with HIV infection suggest an estimated mean lifetime cost of treating one person as £360,800.[31] Therefore, if around 3000 men are newly infected each year, new direct lifetime costs relating to their treatment alone will amount to around £1.1B. If generic drugs replace patented drugs, estimated mean lifetime costs could fall to £179,000. Critically, these costs do not include social costs associated with living with a HIV infection, or the associated cost savings associated with reduced onwards transmission via access to effective treatment (e.g. through TasP). Costs are associated with wider NHS burden.

Current guidelines for human immunodeficiency virus infection prevention among men who have sex with men

There is no single contemporary UK-wide guidance relating to HIV infection prevention among MSM, although the European Centre for Disease Prevention and Control has recently published comprehensive STI and HIV infection prevention guidance.[32] At the level of individual nation states, and some local areas, a range of key documents exist which suggest both broad and specific approaches to HIV infection prevention.

In Scotland, the *Good Practice Guidance on HIV Prevention in Men who have Sex with Men (MSM): Health Protection Network Scottish Guidance*[33] details the importance of combination prevention as an overall perspective within which to understand the potential combination of HIV infection prevention approaches. Combination prevention details how biomedical interventions, such as PrEP, must be thought about alongside wider structural interventions that aim to address the multiple and concurrent determinants of HIV infection risk-related behaviour. In turn, these wider interventions addressing the distal determinants of HIV infection risk (e.g. reducing homophobia or hegemonic masculinity) should be considered alongside the role of behavioural interventions (such as those being examined in this review). Behavioural interventions focus on how the determinants of sexual risk are experienced by the individual within their own intrasubjective world. As such, they focus on addressing the proximal determinants of HIV infection risk. The Scottish guidance details the importance of the full range of prevention approaches. It details the provision of condoms, post-exposure prophylaxis and HIV infection treatment for people living with HIV as a prevention. It explicitly suggests that focused brief or intensive behaviour change interventions are provided, and based on the acquisition of interpersonal skills and increasing motivation to adopt safer sexual behaviours. It also recommends that these interventions are theoretically informed. It goes on to suggest that these behavioural interventions are provided by staff who have gained competency in their provision

through training. Finally, the guidance details the importance of interventions that address the wider social and cultural determinants of HIV-related risk.

At a fundamental level the combination prevention approach recognises that no single approach to HIV infection prevention will be sufficient to end HIV transmission and harnessing the synergistic effects of multiple prevention strategies as impact on each other promises to have the greatest effect on reducing HIV transmission. The effectiveness of approaches which address the distal determinants of HIV risk at the societal level, for example, is likely to be boosted by individual-level behaviour change interventions that focus on specific subpopulations. In turn, individual-level behaviour change interventions, targeted at those most at risk, are likely to be boosted by effective biomedical approaches to HIV infection prevention. Critically, the logic of the combination prevention approach also exposes the dangers of any singular approach to HIV infection prevention. If biomedical approaches, such as PrEP, for example, do not engage with psychological factors (such as risk perception) they may amplify health inequalities. Equally, if individual-level interventions do not engage with the wider social context (such as health literacy or cultures of masculinity) they too may exacerbate inequities within sexual health.

In England, HIV infection prevention guidance has focused almost solely on biomedical interventions to date and has not addressed behavioural- or structural-level interventions, or the interplay between them. The NICE HIV infection testing guidance[24] was intended to increase the effectiveness of testing as the major approach to HIV infection prevention among MSM in England. NICE's recommendations included the promotion of HIV infection testing in a range of settings, promoting testing in specialist sexual health services, testing in primary and secondary care, outreach and point-of-care testing and promoting repeat testing. Again, as mentioned in *The health problem*, developments in new technologies (e.g. self-testing, PrEP and TasP) have rendered this guidance as outdated.

More recently, at regional level, in 2013 London Directors of Public Health and London Councils collaborated on *HIV Prevention Needs Assessment for London*.[34] The authors note major limitations with regard to existing evidence with which to shape the needs assessment, including the lack of information concerning cost-effectiveness of HIV infection prevention interventions, a lack of focus on theories of behaviour change and a lack of focus on contemporary issues regarding HIV risk. The accompanying evidence synthesis is briefly described in *Table 1*; however, the consortium makes a number of broad recommendations for commissioning of HIV infection prevention services, again intended to be tailored to the specific local context. The report recommends that:

> *[W]hen commissioning HIV prevention interventions, commissioners should consider a 'combination' approach, capitalising on the multiple available prevention interventions now available, that are evidence-based and focused on knowledge, skills and behaviours as well as access to high quality services. These interventions should be targeted to the right populations, delivered at sufficient scale to maximise their impact, and should address both primary and secondary prevention.*
>
> *HIV Prevention Needs Assessment for London, p. 44*[34]

In addition, the report outlined a number of key areas that should provide a focus for prevention, including HIV infection testing, condom promotion and provision, harm reduction approaches to drug treatment, public and patient engagement, and the use of the digital media and associated technologies.

HIV Prevention England has been the national HIV infection prevention programme in England. Funded by Public Health England, it delivers a nationally co-ordinated programme of HIV infection prevention work with UK-based black African people and MSM. It aims to increase HIV infection testing and support behaviour change (such as increased and correct condom use) to prevent HIV transmission. It is designed to complement locally commissioned infection prevention in areas of higher prevalence, including behavioural change interventions (www.hivpreventionengland.org.uk).

In 2007, NICE produced public health guidelines entitled *Prevention of STIs and under 18 conceptions* (PH 3) (www.nice.org.uk/guidance/ph3).[35] MSM is one of the key target populations of this guidance, which recommends risk assessment and delivery of one-to-one structured discussions with those identified as being at high risk. Aimed primarily at health professionals trained in sexual health, the guidelines recommend that the discussions be structured on the basis of behaviour change theories; addressing factors that can help reduce risk-taking; and improving self-efficacy and motivation. The session should last at least 15–20 minutes, with the number of sessions depending on individual need. The range of suggested behaviour change techniques (BCTs) are based on Conner and Norman's *Predicting Health Behaviour*.[36]

Currently, the NHS England's HIV Clinical Reference Group is formulating policy in relation to HIV infection prevention utilising the biomedical infection prevention interventions of both TasP and PrEP. It is unclear at present whether or not this policy will include the integration of behavioural and other psychosocial approaches.

In summary, there is no contemporary overarching UK guidance that describes and recommends effective HIV infection prevention interventions for MSM in the UK. In Scotland, there is some guidance specifically concerning HIV infection prevention among MSM; however, this is outdated. In regional areas, such as London, there are complementary approaches providing some guidance as to the provision of HIV infection prevention. English HIV infection prevention guidance has focused particularly around HIV infection testing,[24] with some guidance on behaviour change, and awaited policy on biomedical interventions such as antiretroviral drug therapy. Again, given the pace of change within the HIV infection prevention field, this guidance is now outdated and is currently being refreshed.

Current service provision

Historically, and currently, HIV infection prevention has been delivered by a broad range of stakeholders. HIV infection prevention has its origins in the 'grass roots' gay community organisation-led initiatives, which gradually over time have become professionalised (see Flowers[37] for an overview of these changes). However, the delivery of HIV infection prevention services remains distinctly heterogeneous, with third-sector organisations actively involved [e.g. Gay Men Fighting Acquired immune deficiency syndrome (AIDS)], and commissioned by NHS/local authorities, as well as being provided by professional practitioners (e.g. sexual health advisors) through NHS services.

The relationship between infection prevention guidance and the commissioning and provision of prevention services remains complex in the UK. As detailed in *Current guidelines for human immunodeficiency virus infection prevention among men who have sex with men*, there is a lack of overall, contemporary guidance and little evidence of a co-ordinated approach to HIV infection prevention among MSM. This represents a fundamental challenge for standardising HIV infection prevention, assessing its effectiveness and ensuring the implementation of the best evidence-based initiatives, their tailoring to local contexts and epidemics, the routine collection of robust data and the collation of, and access to, cumulative knowledge.

It is only within the NHS that attempts to standardise HIV infection prevention and guarantee minimum standards of prevention have been made. Critically, these do not specifically address the MSM population and do not reflect many of the contemporary issues outlined in *The health problem*. Of particular note are NHS Healthcare Improvement Scotland's *Standards for Human Immunodeficiency Virus (HIV) Services*[38] and the *UK National Guideline on Safer Sex Advice*.[39] Of note, the latter, while providing evidence-based recommendations, has a remit that covers a range of STIs (i.e. it is not solely concerned with HIV infection prevention). Moreover, it also addresses sexual health interventions delivered within GUM settings alone.

The health-care improvement standards are applicable to all NHS boards with responsibility for delivering HIV services in Scotland. This includes prevention directly provided by, or secured on behalf of, NHS boards. They apply to primary, secondary and tertiary care settings. The standards provide detail of general

recommendations for HIV infection prevention; prevention standards for people living with HIV; and, finally, service provision which addresses behavioural interventions. Audits or assessments of compliance with the standards are not available. The standards state that 'NHS boards provide access to HIV risk reduction behaviour change interventions'.[38]

The *UK National Guideline on Safer Sex Advice*[39] focuses on safer sex advice and behavioural interventions that are delivered within UK GUM clinics. Similar to the health-care improvement standards it does not assess, or provide, MSM population-specific guidance relating to the provision of behaviour change interventions. The guidance focuses on six key recommendations, which provide a further level of detail concerning the scope and delivery of behavioural interventions to reduce onwards transmission of HIV. Recommendations include the need for intensive multisession, evidence-based behaviour change interventions targeting individuals and focusing on skills acquisition, enhancing communication skills and increasing motivation to adopt safer sexual behaviours should be available directly or by referral in all GUM clinics. They suggest that motivational interview techniques should be used as part of an intensive course of risk reduction counselling in MSM at high risk of HIV infection. Brief (15–20 minutes) evidence-based behaviour change interventions targeting individuals and focusing on skills acquisition, enhancing communication skills and increasing motivation to adopt safer sexual behaviours [using techniques such as motivational interviewing (MI)] should be provided as part of routine care of those at elevated risk of STIs and HIV infection in GUM clinics. The delivery of safer sex advice, including condom demonstration, based on the characteristics of effective brief behaviour change interventions, should be part of the routine care of all those at continued risk of infection/transmission in GUM clinics. The provision of accurate, detailed and tailored information on safer sex should form part of all sexual health consultations. MI should be provided by clinic staff who have gained competency in its provision through training.

Desai *et al.*[40] report and audit the provision of behavioural interventions following the implementation of the UK guidance relating to safer sex.[39] The authors reported that, in an assessment of 24 sentinel GUM clinics, there was a low level of offer and uptake of behaviour change interventions to higher-risk MSM. They note that reasons for this poor compliance may relate to patient factors (e.g. only around 42% of MSM accepted the offer of any behaviour change intervention). However, the lack of offer, and uptake, may also relate to clinic staff's perception of a lack of training or resource shortage. Many of these factors are also explored in *Chapter 7*. Interestingly, Desai *et al.*[40] also examined differences between men deemed at risk and those deemed not to be at risk. They explored whether or not these risk assessments related to the offer of behavioural interventions. They found that significantly more MSM reporting unprotected anal intercourse (UAI) were offered behavioural interventions, especially MI.

Overview of current possible approaches to human immunodeficiency virus infection risk reduction

Current service provision shows there is no definitive guidance relating to the approaches that may, or may not, be useful in relation to behaviour change interventions among MSM. In this section we provide a brief overview of potential interventions, which are sometimes offered within prevention and testing services.

Cognitive–behavioural therapy (CBT) is an intervention originally developed to treat depression. The goal is to change unhelpful thinking (i.e. cognitions) and related behaviours. It involves several phases including assessment, reconceptualising thinking and behaviour, and developing and practising skills to change behaviour. Behaviour change is achieved through a number of exercises both during the therapy sessions and between sessions ('homework'). The number of sessions can vary, but CBT can be delivered in as few as six sessions.

Motivational interviewing was developed by Miller and Rollnick,[41] originally to counsel clients with alcoholism,[41] and has been recommended in national guidelines for safe sex (e.g. in the UK)[39] and by the US Centers for Disease Control and Prevention (CDC). It is defined as 'directive, client-centred

counselling . . . for eliciting behavior change by helping clients to explore and resolve ambivalence'.[41] The goal is to increase client motivation so that change is achieved by the individual rather than imposed externally. It incorporates counselling strategies such as assessing and reflecting readiness to change, using decisional balance exercises to increase motivation for change, and building self-efficacy for change by identifying perceived barriers. Judgemental statements about any particular behaviours are avoided in order to reduce the risk of increasing resistance or defensiveness. An individual's freedom to choose, as well as their responsibility for their own choices, is emphasised.

Motivational enhancement therapy (MET) is an adapted version of MI. It is a systematic approach designed to produce rapid, internally motivated change using MI techniques.

Commonly, MI and MET interventions are brief and provided over one or two sessions. They can be delivered as a freestanding intervention and can be delivered prior to, or integrated with, other treatments (e.g. with the use of PrEP).

In summary, although standards of HIV infection prevention are available, they are not available UK-wide and are not aimed at specific populations (e.g. MSM). There is limited and outdated evidence concerning the implementation of such guidance within English GUM settings and this shows poor compliance with the recommended evidence-informed standards.

Existing evidence syntheses

Several systematic reviews have attempted to summarise existing literature and provide guidance on HIV infection prevention among MSM (*Table 1*). These include overview of systematic reviews,[55] narrative reviews of primary studies[34] and meta-analyses.[56]

As outlined at the start of *Chapter 1*, there are particular complexities with regard to HIV infection prevention, and the pace and scope of its changes. At the end of the 20th century, effective treatments for HIV infection became widely available, profoundly changing the nature and meaning of being infected with HIV from a 'death sentence' to a chronic, manageable condition.[60] As a result of this loss of the 'perceived severity' of HIV infection,[61] evidence concerning the effectiveness of behaviour change interventions is not transferable from the pre-treatment era. Several existing systematic reviews straddle this watershed moment in which effective treatment for HIV infections became widely available in the developed world.[46,47,50,53,57] These studies mix knowledge concerning behaviour change interventions, designed to reduce HIV infection risks with high perceived severity, with those that are designed to reduce HIV infection risks with lower perceived severity. Equally, systematic reviews of behavioural interventions exist for a range of populations, but do not solely focus on MSM[42,45,48,49,51,54] and this limits the direct translation of findings to this specific population.

Table 1 also shows the ongoing methodological problems associated with the existing evidence. These relate to issues such as conflicting and limited evidence:[43] on the one hand, the heterogeneity of populations included in studies and, on the other hand, where population criteria is more tightly specified, the small number of studies available for review.[48,62] Many of the studies available suffer from high or unclear risk of bias.[62] Primary studies often suffer from high attrition,[48,53] a lack of statistical power,[48] limited follow-up periods,[48] heterogeneity of intervention content,[54] heterogeneity of cultural context regarding implementation,[49] differential attrition between intervention and control, a lack of information regarding cost-effectiveness,[34] a lack of focus relating to theories of behaviour change,[34] a lack of focus regarding the complexity and changing nature of HIV risk-related behaviours,[34,55] a lack of inclusion of qualitative and mixed-methods studies,[55] and the heterogeneity of outcome measures.[58]

However, overall, these evidence syntheses do suggest cautious support for the efficacy of behavioural interventions among MSM.[34,43,49,55,56,58,59,62] Moreover, they suggest that evidence-based interventions have larger effects than non-evidence-based interventions.[48]

TABLE 1 Recent evidence syntheses

Authors (year of publication)	Inclusion criteria	Design	Constitutive studies	Summary of key findings
Albarracín *et al.* (2005)[42]	To test major theoretical assumptions about behaviour change by examining outcomes and mediating mechanisms of different preventative strategies in interventions, examining differential effects of passive vs. active HIV infection prevention since the beginning of the epidemic	International scope 1988–2003 Range of modes and levels of delivery (e.g. community, face to face, video presentation)	Meta-analysis of 354 intervention studies and 99 control groups	The most effective interventions were those that contained attitudinal arguments, educational information, behavioural skills arguments and behavioural skills training The least effective were those that attempted to induce fear of HIV The impact of the interventions and the different strategies behind them was contingent on the gender, age, ethnicity, risk group and past condom use of the target audience in ways that illuminate the direction of future preventative efforts Limitations include: • the correlational nature of the results • the validity of condom use self-reports • the impossibility of analysing complex interactions between interventions and subpopulations • the selection of behavioural measures • the insufficient number of effect sizes to estimate the population variance precisely
Berg *et al.* (2011)[43]	The effectiveness of behavioural interventions adapting the principles and techniques of MI on HIV infection risk-related behaviours for MSM	International scope 1983–2010: earliest study was in 2001 HIV-positive and HIV-negative men MI-based counselling and its adaptations (such as brief MI and MET)	A systematic review 10 randomised controlled trials with low to moderate quality	This systematic review demonstrated uncertain effectiveness of MI as an intervention strategy for unsafe sexual and substance use behaviours among MSM MI was largely equivalent to other active and minimal treatments for HIV-related behaviours MI as an intervention for all HIV infection risk-related behaviours among all groups of MSM should not be dismissed There is a need for continued work to craft more effective HIV infection prevention approaches among MSM Limitations include: • heterogeneous composition characteristics of the groups and control conditions • conflicting and limited data make it difficult to draw firm conclusions about whether or not MI enhances motivation for changing sexual behaviours among MSM

Authors (year of publication)	Inclusion criteria	Design	Constitutive studies	Summary of key findings
Berg (2009)[44]	All forms of behavioural and psychosocial interventions designed to promote safer sexual risk-related behaviours among MSM were eligible for inclusion	MSM living in Europe, and to identify intervention characteristics associated with effectiveness 2000–9 HIV-positive and HIV-negative men No restrictions in level or mode of deliver	Results taken from six controlled studies, involving a total of 4111 participants at entry from four different European countries were summarised	The pooled effect estimate of the four interventions for which data were available suggested that MSM who participate in HIV infection or STI prevention initiatives may be somewhat less likely to report UAI Limitations include the limited number of studies available. In addition, the results showed that there was 'high' or 'unclear' risk of bias in one or more of the assessed domains in all studies
Crepaz *et al.* (2006)[45]	Determine overall efficacy in reducing HIV infection risk-related behaviours of HIV infection interventions for PLWH and identify intervention characteristics associated with efficacy	1988–2004 USA scope PLWH Interventions predominantly delivered by health-care providers/ counsellors or peers; delivered to small groups	Meta-analysis of 12 controlled trials	Interventions significantly reduced sexual risk-related behaviours if they were: 1. based on behavioural theory 2. designed to change specifically HIV transmission risk-related behaviours 3. delivered by health-care providers or counsellors 4. delivered to individuals 5. delivered in an intensive manner 6. delivered in settings where PLWH receive routine services or medical care 7. provided skills building 8. addressed a myriad of issues related to mental health, medication adherence, and HIV Limitations noted include: • the small number of trials concerning subgroups such as MSM • the over-reliance on self-reported data • a lack of blinding • most studies were carried out in the USA • under-reporting of data relating to a wide variety of issues (e.g. serostatus of partner, number of partners with whom unprotected intercourse occurred, cost data)

continued

TABLE 1 Recent evidence syntheses (*continued*)

Authors (year of publication)	Inclusion criteria	Design	Constitutive studies	Summary of key findings
Ellis *et al.* (2003)[46]	The effectiveness of any interventions with the goal of reducing the sexual risk of transmitting or acquiring a HIV infection	International scope 1994–2001 UK priority populations: MSM, African communities, CSWs, people with HIV infection	Review of reviews	Evidence for the greater effectiveness of multicomponent interventions in relation to group work with MSM, although very little review-level evidence relevant to UK MSM overall
		Focus on HIV voluntary counselling and testing Range of delivery modes/levels assessed (e.g. individual, group, community, multisessional, etc.)	Nine reviews	Very little review-level evidence about the impact of interventions on the modifying factors which influence sexual behaviour Very little review-level evidence relevant to UK CSWs No review-level evidence relevant to UK African communities No review-level evidence about interventions with people with HIV Voluntary counselling and testing, when combined with another component, is more effective than on its own. However, no review-level evidence to support or discount the effectiveness of any other multicomponent interventions with MSM, CSWs, Africans or people with HIV Limitations include: • the lack of transparent description of intervention content and details of delivery • lack of UK-based studies • biased samples • little attention to the reduction in health inequalities • little attention to subpopulations of MSM

Authors (year of publication)	Inclusion criteria	Design	Constitutive studies	Summary of key findings
Herbst *et al.* (2005)[47]	Effectiveness of interventions in reducing risky sexual behaviours among MSM that potentially lead to HIV transmission and infection, to identify population characteristics, study design, intervention features or groups of factors that are associated with intervention efficacy	International scope 1989–2003 MSM Individual-, group- and community-level interventions	Meta-analysis of 33 studies	Interventions successful in reducing risky sexual behaviour were based on theory-based models, included interpersonal skills training, incorporated several delivery methods and were delivered over multiple sessions spanning a minimum of 3 weeks Limitations include: • the reliance on self-reported data • a lack of reporting of variables (such as gay community involvement, culture, religion, partner selection) precludes more detailed examination of intervention effects • a lack of reporting of key intervention elements • the clustering of many intervention characteristics across interventions precluded the use more sophisticated meta-analytic procedures, such as metaregression, to disentangle the independent effects or interactions among study characteristics
Higa *et al.* (2013)[48]	To identify challenges of demonstrating efficacy of HIV behavioural interventions for MSM To identify reasons for the small number of EBIs for MSM	USA only January 1988 and December 2010	Systematic review of 33 studies addressing methodology	9/33 studies were considered EBIs, whereas 24/33 were non-EBIs. Non-EBIs had multiple methodological limitations and the most common was not finding a significant positive effect. Compared with EBIs, non-EBIs were less likely to use peer intervention deliverers, include sexual communication in their interventions, and intervene at the community level Incorporating characteristics associated with EBIs may strengthen behavioural interventions for MSM More EBIs are needed for substance-using MSM, MSM of colour, MSM residing in the south and MSM in couples Excluded interventions that were not specifically designed for MSM but had substantial numbers of MSM in their samples (e.g. HIV clinic patients) The authors note problems in the field relating to small sample size, attrition, underpowered studies and limited follow-up periods

continued

TABLE 1 Recent evidence syntheses (*continued*)

Authors (year of publication)	Inclusion criteria	Design	Constitutive studies	Summary of key findings
Jbilou *et al.* (2013)[49]	Evidence on best practice programmes for sexual and reproductive health promotion	International scope	Scoping review of 50 studies	Interventions designed for men only showed significantly greater effectiveness than interventions targeting both men and women
	Targeting men	2000–12		Most interventions have shown to be effective in improving knowledge, attitudes and sexual behaviours in men
	Focus on gendered differences among effective interventions for diverse populations			None of the studies explored predictors of non-compliance to safe sex and HIV infection testing behaviour among men in general. But, some of them have highlighted barriers to, and facilitators of, achieving the goal of a HIV-free generation among sexual minority communities including MSM
				e-Health prevention interventions seem particularly effective among men
				Limitations include: • the diversity of interventions that can be reviewed • the heterogeneity of cultural contexts in which interventions are reviewed
Johnson *et al.* (2008)[50]	All behavioural interventions aimed at reducing risk for HIV or STD transmission among MSM	International scope	44 studies evaluating	Behavioural interventions reduce self-reported UAI among MSM
		1988–2007		Clear and focused reduction messages are useful
		Individual-, small group- and community-level interventions	58 interventions	Intervention effects were smaller when interventions were compared with control conditions with active content; the latter demand larger sample sizes
				Limitations include: • the issue of differential retention rates between interventions and controls • the challenges of the complex ways that MSM may reduce HIV risks

Authors (year of publication)	Inclusion criteria	Design	Constitutive studies	Summary of key findings
Johnson *et al.* (2006)[51]	Degree to which prevention programmes for HIV-positive people are efficacious	International scope (although predominantly USA) 1993–2004 HIV-positive people	Meta-analysis of 15 studies	Across the studies, intervention participants exhibited lowered sexual risk relative to control participants on condom use but not for number of sexual partners Interventions were more successful at increasing condom use if: • the sample included fewer MSM • the sample was younger • the interventions included motivational and skills components Such interventions have been less effective for older samples, suggesting the need for further refinement to enhance their efficacy. HIV-positive MSM appear to have benefited less from extant risk reduction interventions Limitations include an over-reliance on studies from the USA
Johnson *et al.* (2003)[52]	Behavioural and social interventions targeting MSM	International scope 1988–97 HIV-positive and HIV-negative men	13 eligible studies	The summary effect of these diverse interventions was indicated that 23% fewer men reported unprotected anal sex after receiving the intervention than after the control condition Limitations include: • high overall attrition • high differential attrition • small number of studies • homogeneity of results
Johnson *et al.* (2002)[53]	Effectiveness of HIV infection prevention behavioural interventions for MSM	1989–97 USA only MSM Small group- and community-level interventions	Meta-analysis of nine studies	Most favourable effects were observed among interventions that: • promoted interpersonal skills • were delivered in community-level formats • focused on younger populations or those at higher behavioural risk Limitations include: • the small number of studies • studies had high/differential attrition

continued

TABLE 1 Recent evidence syntheses (*continued*)

Authors (year of publication)	Inclusion criteria	Design	Constitutive studies	Summary of key findings
Melendez-Torres and Bonell (2014)[54]	Effectiveness of CBT interventions for HIV infection risk reduction in substance-using MSM	USA only No limits on time/year but studies identified were published between 2005 and 2010 Substance-using MSM	Systematic review of three studies	Evidence that although CBT may reduce UAI in substance-using MSM, it is unclear if CBT is more effective than mere assessment Reductions in UAI may merely reflect regression to the mean. Heterogeneity in trial design, comparators and population poses substantial difficulties for generalisability Limitations include: • the small pool of heterogeneous studies • use of a strict definition of CBT
Rashbrook (2013)[34]	Not reported	International scope 2011–13 HIV-positive and HIV-negative men	Review of reviews Unclear	Limited evidence of effectiveness for motivational interventions, and evidence for education and health promotion, supportive approaches, media interventions and PrEP Limitations include a lack of: • information concerning cost-effectiveness of HIV infection prevention interventions • focus on theories of behaviour change • focus on contemporary issues regarding HIV infection risk

Authors (year of publication)	Inclusion criteria	Design	Constitutive studies	Summary of key findings
Lorimer *et al.* (2013)[55]	MSM and behavioural interventions	International scope 2000–12 HIV-positive and HIV-negative men Comparison of effectiveness via mode of delivery as individual, group and community	Review of reviews A narrative synthesis across the four included meta-analyses (102 studies; 52 independent studies)	Strong and consistent evidence for group- and community-level interventions being associated with reductions in UAI (27–30% and 30%, respectively) and increases in condom use among MSM Inconsistent evidence for the effectiveness of individual-level interventions Skills-building, trained professionals delivering the training and theory-based interventions were also associated with effectiveness Demonstrable need for evidence-based interventions to utilise contemporary knowledge and issues Limitations include: • the inclusion of data from previous HIV infection prevention eras • the lack of interventions that utilise social media • questionable transferability of evidence across cultural changes • the lack of inclusion of the insights of qualitative and mixed-method research • the challenges of selecting outcomes which reflect contemporary issues

continued

TABLE 1 Recent evidence syntheses (*continued*)

Authors (year of publication)	Inclusion criteria	Design	Constitutive studies	Summary of key findings
Lu *et al.* (2013)[56]	Behavioural interventions	China only Unclear time period HIV-positive and HIV-negative men Evaluation of effects of interventions on a broad range of outcome measures	Systematic review and meta-analysis 34 studies, including two randomised controlled trials	Studies showed an increase in consistent condom use with any male sexual partners, regular sexual partners and casual sexual partners The analysis of 10 studies that measured the impact on uptake of HIV infection testing also showed a positive result Risk reduction interventions also improved HIV/AIDS-related knowledge and attitudes, but did not reduce prevalence of HIV and syphilis infections Limitations include a lack of: • control groups • randomisation
Rees *et al.* (2004)[57]	Effective and appropriate approaches for increasing HIV-related sexual health among MSM	1997–2002 International scope for effectiveness studies UK scope for qualitative studies MSM Individual and group interventions Peers and professionals	Synthesis of quantitative (effectiveness trials) and qualitative (views of MSM) studies Meta-analysis and systematic review of eight studies Synthesis with 10 qualitative studies	Counselling or workshops based on cognitive–behavioural techniques for MSM who are at high risk appears to be effective in reducing the number of men reporting serodiscordant or unknown status UAI when compared with standard counselling No evidence of effect on casual UAI of counselling or workshops that contextualise sexual risks No evidence of the effect of UK peer-delivered community-based interventions was found for any of the prioritised outcomes. The 'diffusion of innovation' that underpins some of these interventions may not always have occurred as planned. It is also possible that structural and cultural barriers exist to such interventions in some situations in the UK Themes identified in qualitative studies fell into three broad categories: 1. 'perceptions of sex, self and others in a risky world' 2. 'engaging with sex and HIV' 3. 'experiences of support, advice and information'

Authors (year of publication)	Inclusion criteria	Design	Constitutive studies	Summary of key findings
Schnall *et al.* (2014)[58]	e-Health interventions for MSM	e-Health interventions only January 2000 to April 2014 HIV-positive and HIV-negative men	Systematic review of 13 studies	There is evidence that e-health for HIV infection prevention in high-risk MSM has the potential to be effective Effectiveness has been demonstrated, in the short term, for reducing HIV risk-related behaviours and increasing testing rates Limitations include the heterogeneity of interventions and outcomes
Strömdahl *et al.* (2015)[59]	Non-meta-analytic review of the efficacy and implementation of studies in Europe	European settings To 2013 HIV-positive and HIV-negative men	24 interventions (biomedical, behavioural and structural)	Condom use, peer outreach, peer-led groups, and using universal coverage of antiretroviral drug treatment and treatment are highly recommended Voluntary counselling and testing for HIV, using condom-compatible lubricant, using post-exposure prophylaxis, and individual counselling for MSM living with HIV recommended Possible recommendation for individual counselling for MSM, peer-led group interventions for men living with HIV, internet-based HIV infection prevention messages, interventions in sex on premises venues, social marketing interventions, PrEP and voluntary circumcision A paucity of implementation data was found in the EU/EEA setting

CSW, commercial sex workers; EBI, evidence-based intervention; PLWH, people living with HIV; STD, sexually transmitted disease.

Rationale for current evidence synthesis

The existing evidence is insufficient to direct future policy and practice, or to determine which specific candidate interventions to reduce HIV transmission should be tested in future trials. The findings of existing reviews tend to be difficult to translate to a contemporary UK context for a number of reasons. For example, their broad operationalisation of behavioural interventions typified by a tripartite distinction of modality of delivery as 'individual level', 'group level' and 'community level' is not helpful. These distinctions are often used in reviews to compare approaches to determine the best use of resources rather than to provide an evidence base that might be useful in delivering the synergistic effects of combinations of interventions. Given both the heterogeneity of the existing reviews and the key changes to HIV infection prevention outlined earlier in the report (see *Table 1*), further broad-level evidence synthesis, or reviews of reviews, are unlikely to demonstrate any additional contribution to shaping HIV contemporary infection prevention policy and practice. They have proved excellent in directing HIV infection prevention in broad ways, but they have not delivered in terms of the specificity of the cumulative knowledge they represent, for example detailing the particular content of recommended interventions.

There is a clear need to extract useful knowledge from the existing evidence through focusing more specifically in the available literature on a number of key dimensions.

Population factors

The heterogeneity of the MSM population (in terms of sociodemographic, psychosocial and behavioural factors) demands a review that is as inclusive as possible with regard to the MSM population. This will enable the most inclusive use of the literature and maximise the applicability of the reviews findings to UK populations.

While operationalising an inclusive approach to MSM, however, demographic factors should not limit the potential of studies to be included in the review. However, given the focus on behavioural interventions, a number of psychosocial and sociocultural factors are important in shaping inclusion and exclusion criteria for systematic reviews. Some populations of MSM have clear psychological and social needs that are distinct from those of other MSM and make the transfer of knowledge between samples problematic. For example, some populations of MSM have unique material needs and/or life experiences that merit distinct consideration, such as incarcerated populations, those in residential care and those who are homeless. Equally, for some populations of MSM, the social context of sexual conduct (e.g. the influence of power and gender) may be so distinct from that of other populations of MSM that there may be challenges in terms of the transferability of knowledge from intervention trials in these populations to wider populations of MSM, for example those engaged in commercial sex work, those who are victims of sexual or domestic abuse or violence or those MSM who are transgender. We fully acknowledge that several of these factors are likely to be episodic or infrequent in the MSM population and that interventions aimed at the general population of MSM will also reach them. However, the reverse of this logic is more problematic, transferring evidence from studies that only recruit commercial sex workers or victims of sexual assault to the general MSM population may fundamentally distort the applicability of findings.

Other cultural changes including, but not restricted to, the constantly evolving change in interaction through social media, changes in supply and use of established recreational drugs, the constant stream of newly available new psychoactive substances, the rise in 'chemsex'[19] and the increasing prevalence of intravenous drug use among the general population of MSM, necessitates a systematic review capable of shaping current HIV infection prevention policy and practice that reflects these population trends. Such a review would have to refine inclusion criteria that maximised the use of available literature yet which did not assume the transferability of knowledge between evaluations among distinct populations, such as those receiving intensive interventions for their drug use. For these last populations, drug use may well be the primary of focus of behaviour change rather than HIV risk-related behaviour per se. In this way,

a systematic review is needed that includes studies sampling MSM who engage in drug use episodically, but excludes those who were recruited into trials solely because of their problematic drug use.

An additional critical factor that shaped the scope of the original commissioning brief is the issue of HIV infection status. It is widely acknowledged that the HIV infection prevention needs of HIV-positive men are distinct from those of HIV-negative or untested MSM and merit a particular focus for HIV infection prevention, and subsequent systematic reviews and meta-analyses.[45,63,64] HIV-positive and HIV-negative men differ on a number of psychosocial, behavioural and sociodemographic variables.[65–67] Engagement in HIV risk-related behaviour differs according to HIV status on a fundamental level: for the HIV-positive person risks are focused on potentially infecting another person (i.e. relatively little impact to self), and for the HIV-negative person risks are focused on the potential for them to become infected (i.e. relatively large impact on self). Interestingly, to date, no single evidence synthesis has focused only on the HIV-negative population of MSM. Once more there are a number of complex issues, both practical and conceptual, that relate to how such a focus on the HIV-negative population could be implemented. These include (1) the meaning and significance of HIV-negative status, (2) the accuracy of knowledge regarding HIV status and (3) the role of HIV infection testing in shaping perceptions of HIV infection status and HIV-negative identity. Given their complexity, each of these issues is introduced in the following sections.

The meaning and significance of HIV-negative status have arguably changed in recent years. Changes in the psychosocial and sociocultural context of HIV infection prevention suggest that seroadaptive behaviours are likely to be increasingly important in HIV infection prevention. Moreover, they will be increasingly important in light of the prominence of biomedical approaches to infection prevention. Historically, HIV-positive status has been clearly associated with a HIV-positive identity. HIV positivity has a long history and significance as a 'master identity,' often to the detriment of those living with HIV.[68] In contrast, HIV negativity has not had the same historical significance and meaning. However, the social significance of HIV-negative status is arguably increasing. The issue of eligibility for PrEP, for example, or the increasing importance of seroadaptive behaviours, increases in the prominence of HIV infection testing per se and recency of HIV infection testing (behaviours of relevance only to those who are HIV negative), and increases in the use of the social media, which often ask for people to be explicit about their HIV status, have potentially led HIV-negative status to become an identity in new ways. Moreover, identity can represent a focus for intervention, as identity is central to a whole group of BCTs. In this way, interventions that focus on the HIV negative and enable them to stay HIV negative represent a core, and as yet unexplored, focus for reducing onwards infection.

However, HIV-negative status is different from HIV-positive status in that the latter is not amenable to change. HIV-negative status and any concomitant identity are only as accurate as the last HIV infection test results that people have received. There is variation in the ability of different testing technologies to identify recent HIV infection, with older tests accurately reflecting HIV status only around 3 months prior to a testing event. In this way, depending on the specific testing technology, the timing of HIV risk-related behaviour preceding the test and the time that has elapsed since the most recent test, the accuracy of a HIV infection status may vary considerably.

The HIV infection testing process represents a complex intervention its own right. Some forms of delivery of the testing process necessitate a focused interaction with a health professional, representing a teachable moment. Teachable moments are those events or sets of circumstances in which individuals may be particularly responsive to behaviour change interventions. Although the concept lacks internal coherence, it is intuitively plausible. Moreover, it has a resonance with concepts such as 'cues to action' from the health belief model,[61] and also chimes with frameworks such as 'stages of change', which also provide a heterogeneous account of people's readiness and willingness to engage with behaviour change interventions. Lawson and Flocke[69] describe a teachable moment as something cocreated through interaction, and highlight the importance of communication between health professional and patient.[69]

Like the HIV infection testing process, receiving negative HIV infection test results also represents a teachable moment. It can be thought of as a BCT in and of itself (i.e. 'biofeedback'[70,71]) and, if delivered in a health professional context, also can be thought of as including the BCT 'credible source' in which verbal communication is likely to occur in favour of behaviour change.[70] Equally, there is literature that suggests the ongoing receipt of negative test results in the light of ongoing high-risk behaviour represents reinforcement of perceived invulnerability and unrealistic optimism. However, it could be argued that the receipt of negative test results represents less of a teachable moment than the testing process itself, as if the patient has been concerned and anxious about their risk-related behaviour, it may be that they are so relieved at hearing negative results that they lack the cognitive capacity to engage with the offer of a brief behaviour change intervention.

This complexity means that any systematic review with a focus on HIV-negative MSM must achieve a difficult balance in setting inclusion criteria. The most reliable HIV-negative populations are those who take part in interventions delivered immediately after receipt of a HIV-negative test result. However, very few trials focus on recruiting this particular population alone. From a more psychological perspective, it makes sense to transfer knowledge to HIV-negative populations of MSM who think and act as if they are HIV negative, while acknowledging that many may actually have seroconverted since their last test result. At the same time, and more pragmatically, it is important to consider whether or not knowledge gleaned from studies in which the vast majority of MSM are HIV negative (e.g. by self-report), can usefully be transferred to populations of MSM who have better knowledge of their HIV status.

In relation to these issues and advice from the project management and advisory groups, the current review sought to exclude studies that included HIV-positive men alone, and to exclude studies in which 33% or more of the population were HIV positive.

Rationale for a focus on behaviour change techniques

In recent years there has been an explosion of interest in clarifying, and examining, the specific content of behavioural interventions. To date, much of this work has focused on individual-level interventions and represents a focus on reflective behaviour change interventions, rather than those that are oriented to more non-reflective processes of facilitating behaviour change. BCTs are described as 'the smallest component compatible with retaining the postulated active ingredients that is, the proposed mechanisms of change, and can be used alone or in combination with other BCTs'.[70] The focus on BCTs represents an attempt to develop a common language of intervention content that is concerned with the granularity of intervention detail. There is growing evidence of the feasibility and value of using BCT taxonomies to review behaviour change interventions,[71–75] in order to shape the specificity of future candidate interventions and policy practice. Analyses that examine the content of interventions at this detailed level are likely to yield results that are similarly detailed. To date, 93 individual BCTs have been identified, and these individual techniques are clustered into 16 distinct groups of BCTs. Further information on the details of BCT is available at www.ucl.ac.uk/behaviour-change-techniques (accessed 26 November 2016).

In contrast to the granularity of the BCT approach, the recent NICE guidelines, *Individual-Level Behaviour Change. External Evidence Review 1: Review of Current NICE Guidance and Recommendations*,[76] highlight the value of a less myopic perspective and note that it is highly likely that there are synergistic effects of individual BCTs working together and in specific social contexts. They suggest the importance of analysing BCTs in conjunction with the potential moderating effect of other variables (such as mode of delivery and intervention intensity). To date, there has been very little domain-specific developments of BCTs in relation to HIV infection risk reduction and no specific examination of the literature regarding MSM and HIV risk-related behaviours (one study[77] focused on general populations and condom use).

Rationale for a focus on the role of theory

The appropriate use of theory within behaviour change is central to the effective design and evaluation of complex evaluations.[78] A trend towards increasing use of theory in behavioural interventions has been reported.[79] There is no clear consensus regarding whether or not the use of theory in behaviour change interventions enhances their effectiveness. Some authors have indeed found a positive correlation between theory and effectiveness.[80–83] However, others have found that the relationship is not so clear.[84,85] There are clear arguments regarding the reasons why the correct use of theory should improve effectiveness.[78,86,87] For example, outlining a hierarchy of outcomes and selecting a primary outcome or selecting the use of appropriate BCTs should improve intervention effectiveness. Equally, detailing the key mechanisms of behaviour change and enabling intervention evaluation designs to assess the role of moderation and mediation factors in tracking intervention effectiveness at an individual level should improve intervention effectiveness considerably.

There are also key reasons why the relationship between theory and effectiveness can be obscured, for example tokenistic or poor operationalisation of theory or, indeed, the inappropriate choice of theory. In relation to these issues, a systematic review is needed that has a distinct focus on understanding the role of theory within interventions, how well, and in which particular ways, theory has been operationalised. Equally, there is a clear need to assess how the patterning of effectiveness is associated with theory use.

Rationale for a focus on modes of delivery

Given the rise of the social media in shaping the sexual cultures of MSM outlined at the start of *Chapter 1* and the increasing prominence of digitally delivered sexual health interventions,[88] there is a demonstrable need for a clear focus on the ways that interventions are delivered. It is also important to assess who delivers interventions and whether or not effectiveness is patterned by the type of interventionist available, as this may have implications for treatment fidelity.

Rationale for expert event

It is vital to extract the most useful evidence relating to cost- and clinical effectiveness of interventions. However, in order for this evidence to be useful in NHS settings, it is also important to assess the transferability of this evidence to contemporary UK settings and to identify the factors that are critical to facilitating the implementation of potential interventions in the near future.

Aims

- To determine the clinical effectiveness of behaviour change interventions to reduce risky sexual behaviour after a negative HIV infection test in MSM.
- To develop a candidate intervention suitable for the UK context.

Objectives

- To map existing evidence on behaviour change interventions to reduce risky sexual behaviour after a negative HIV infection test in MSM.
- To evaluate the clinical effectiveness of behavioural change interventions to reduce risky sexual behaviour after a negative HIV infection test in MSM.

- To identify the most effective component or components within behavioural change interventions in reducing risky HIV infection-related behaviours:
  - model of delivery
  - number and type of BCTs
  - theory-congruent clusters of BCTs.
- To use post hoc realist review methods to further synthesise the evidence in order to develop a candidate intervention.
- To examine the sequential presentation of intervention components in order to develop a candidate intervention.
- To develop a candidate intervention and associated intervention manual.
- Organise and host expert events to enable the translation of findings and further develop a candidate intervention.

Chapter 2 Systematic narrative review and meta-analysis

A systematic review and meta-analysis was undertaken to evaluate the clinical effectiveness of behaviour change interventions to reduce risky sexual behaviour after a negative HIV infection test in MSM. This review was undertaken in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement[89] (see *Appendix 1*). This review was prospectively registered in the PROSPERO database (www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42014009500; accessed 11 September 2016).

Eligibility criteria

Population

All MSM who were HIV negative and eligible for behaviour change interventions were included in the review. Adopting the criteria used in Johnson *et al.*,[50] this review considered only studies in which MSM constituted at least one-third of the study sample or were specifically targeted by the intervention. When non-MSM populations were included, only data specific to the MSM subgroup were used. Studies were included if the majority of men (> 66%) were HIV negative, verified by confirmed status, self-reported status or through testing as part of the study procedures. Studies with no verification of status, either by self-reporting or through testing as part of the study procedures, were excluded. Studies were excluded if they focused exclusively on commercial sex workers, people who are transgender, victims of sexual or domestic abuse or violence, intravenous drug users, those in prison, those in psychiatric facilities or nursing homes or individuals with no fixed address. These groups have distinct needs beyond the scope of the review.

Interventions and comparators

All individual-level behavioural change interventions designed to promote HIV infection risk reduction behaviour were included in this review. In particular, brief behavioural change intervention, defined as any therapeutic or preventative consultation of short duration (1–5 sessions), were considered. No restrictions were applied to the type of intervention setting, mode of delivery or MSM population beyond those listed.

The relevant comparators were usual care or minimal intervention. Studies with the following control conditions were deemed eligible for inclusion if participants:

- were on a waiting list to receive the intervention under study
- were continuing to receive 'usual care'
- received a lesser dose or only some of the core components of the intervention under study (minimal intervention)
- received an entirely different intervention from that under study.

Outcomes

Data on the following outcomes were sought:

- Behavioural: approaches which are known to reduce the risk of HIV acquisition; condom use across all time periods; approaches such as negotiated safety; the uptake of and adherence to PrEP; or combinations of these.
- Biological: HIV/STI incidence.
- Learning: HIV/STI knowledge; condom application skills.

- Cognition: condom use self-efficacy; condom-related attitudes or beliefs; HIV/STI risk perception; or negotiated safety self-efficacy and PrEP self-efficacy.
- Cost-effectiveness: costs, health-care resource use, quality-adjusted life-years and incremental cost-effectiveness ratios.

Types of study

All comparative studies comparing two or more interventions, that is, randomised controlled trials (RCTs) or controlled clinical trials, were considered for inclusion.

Identification of studies

Search strategies were designed to capture the four relevant concept areas: (1) HIV, AIDS, or sexually transmitted disease (infection); (2) prevention research methods (e.g. intervention, education, counselling and evaluation); (3) sex risk-related behaviours and biological outcomes; and (4) target population of MSM. All relevant keywords were combined with appropriate search filters. All searches were carried out between January 2000 and December 2014. We chose to restrict searches from 2000, as the widespread availability of highly active antiretroviral therapy renders the translation of findings from earlier periods of time problematic. English-language restrictions were applied. The MEDLINE search strategy is shown in *Appendix 2*.

Electronic databases

Studies were identified by searches across the following electronic bibliographic databases:

- Applied Social Sciences Index and Abstracts via ProQuest
- British Education Index
- BioMed Central
- Cumulative Index to Nursing and Allied Health Literature via EBSCO*host*
- EMBASE via NHS Knowledge Network
- Education Resources Information Centre (ERIC) via EBSCO*host*
- Health and Medical Complete via ProQuest
- MEDLINE via EBSCO*host*
- PsycARTICLES via ProQuest
- PsycINFO via ProQuest
- PubMed via NCBI
- Social Science Citation Index via Web of Science.

Other sources

The following specialist registers were searched in August 2014, in the same time frame as electronic databases, with the exception of Trials Register of Promoting Health Interventions, as search dates could not be applied, to identify relevant recently completed trials:

- Cochrane Central Register of Controlled Trials
- ClinicalTrials.gov (https://clinicaltrials.gov/)
- Trials Register of Promoting Health Interventions, via the Evidence for Policy and Practice Information and Co-ordinating Centre (http://eppi.ioe.ac.uk)
- World Health Organization's International Clinical Trials Registry Platform (WHO ICTRP) (http://apps.who.int/trialsearch/).

Other searches carried out included those using the University of York CRD Database for assessed economic evaluations, OpenGrey, the CDC HIV/AIDS website and Google Scholar (Google Inc., Mountain View, CA, USA). The reference lists of included papers were also scanned for additional studies.

Screening strategy

The screening of titles and abstracts was carried out by one reviewer, with a 10% subset screened independently and validated by a second reviewer. There was 98% agreement on this subset. All full texts were reviewed independently by two reviewers. Disagreements over inclusion were resolved through consensus and, when necessary, through further discussion with a third member of the review team.

Data extraction

We extracted data on the following: study identifier (author, location, year); study design (method of recruitment, duration of follow-up, outcome measures); participant details (number of participants, age); intervention and comparator details; and details relevant to risk of bias. We also extracted dichotomous data, continuous data, risk ratios and confidence intervals (CIs) on outcomes, when appropriate. Data were extracted from the studies by one reviewer and checked by a second. Any disagreements were resolved through consensus or, if necessary, by referral to a third reviewer.

Assessment of risk of bias

All studies were assessed using the Cochrane risk-of-bias tool (p. 196 in the *Cochrane Handbook for Systematic Reviews of Interventions*).[90] Individual studies were judged to be of high, low or unclear risk of bias according to six domains: selection bias (adequate sequence generation and allocation concealment); performance bias (blinding of participants); detection bias (blinding of outcome assessors); attrition bias (clear account of dropouts and exclusions); and reporting bias (selective outcome reporting). Disagreements over risk of bias were resolved through discussion between primary reviewers and, when necessary, through further discussion with a third member of the review team.

Synthesis of results

Classification of behaviour change techniques

Descriptions of behavioural change intervention content were coded into BCTs using a 93-item revised version of the BCT taxonomy version 1, as proposed by Michie *et al.*[72] Two independent reviewers coded the BCTs. Disagreements and additional BCTs identified were subsequently discussed. Where agreement could not be reached, a third reviewer gave a final rating on the discrepancies between the first two reviewers. BCTs were coded for both interventions and controls.

We present details of those BCTs that were unique to the intervention, that is we disregarded BCTs that were also used in control groups (as the majority of controls were usual care, they did include active BCTs); in this way, we separated what are likely to be the unique effects of the intervention from the effects of the control.

Theory coding assessment

In order to examine the role of theory within interventions, the theory-coding scheme of Michie and Prestwich[86] was adopted. Critically, the approach does not analyse if theory-based interventions per se are more effective than those that are not based on theory. Instead it seeks to examine exactly how theory has been operationalised at a number of levels within an intervention. It assesses how theory has informed the intervention, how theory has been used in the development of interventions, how theory or predictors have been used to select intervention recipients for interventions and how BCTs are related to theories and theoretical constructs (providing a measure of theory-congruent BCTs).

The first 11 items of the 19-item theory-coding assessment were used to assess the relationship between theory and target behaviours and how this can inform intervention development and implementation.[86] These items categorise the role of theory within interventions across a number of dimensions including whether or not a theory or model was mentioned, how theories were used in the intervention design and how intervention evaluations tested theory (e.g. tracking proposed mechanisms of behaviour change). The theory-coding assessment was assessed by two independent reviewers. Disagreements were resolved

through discussion. Any subsequent discrepancies that were not resolved by the two primary reviewers were subject to third-party reviewing to make a final decision regarding discrepant items.

Following Prestwich *et al.*,[85] a score of theory-congruent BCTs was created. This created an overall score of between 0 and 8. For further analysis, see *Exploratory meta-analysis*. Groups of interventions were compared in terms of those who had an overall score of ≥ 4 and those who scored < 4.

Mode of delivery assessment

Mode of intervention delivery was assessed along a number of dimensions: primary delivery mode (e.g. online, face to face or telephone), details of interventionist if applicable (e.g. clinicians, peers, avatars and counsellors), intervention setting (e.g. clinic or domestic), the frequency of intervention sessions (e.g. the number of episodes of intervention delivery) and the intensity of the interventions (e.g. the total time taken to deliver the intervention).

Proximity to testing assessment

As outlined in *Chapter 1*, there is considerable heterogeneity with regard to the ways in which HIV-negative status and concomitant identity is assessed in the wider literature. In order to provide an analytical focus on the issue of proximity to HIV infection testing, a simple scale was designed that provided five distinct categories based on the proximity of intervention delivery to the testing event and, thus, potential accuracy of HIV-negative status: delivery of the intervention immediately after receipt of a negative test result; delivery of the intervention immediately after testing but before a result has been obtained; delivery of the intervention to those who have tested negative within the previous12 months; delivery of the intervention to MSM who have been tested and received a negative test result at any time in the past; and, finally, delivery of the intervention irrespective of the participants' HIV status but with HIV status clearly recorded.

Treatment fidelity assessment

A 30-item treatment fidelity checklist[91] was applied to intervention descriptions and the available manuals and protocols. This checklist assesses whether or not methodological strategies were in place with regard to the following five areas: study design (seven items); interventionist training (seven items); intervention delivery (nine items); intervention receipt (five items); and intervention enactment (two items). The treatment fidelity checklist was scored by two independent reviewers. A third assessor examined all discrepancies and consensus was reached. Percentage scores were calculated for each section to reflect the proportion of items with evidence of at least one treatment fidelity strategy. An overall summary score of $\geq 80\%$ is considered to represent an intervention with a high treatment fidelity rating.[92]

Statistical methods

Individual study characteristics and outcomes were summarised and presented in evidence tables. Narrative synthesis of evidence was carried out. When appropriate data were available, pairwise meta-analysis of behavioural change interventions was carried out based on the random-effects model;[93] this was based on the assumption that the effects being estimated in the included studies are not identical but follow the same distribution. For dichotomous outcomes, risk ratios, and for continuous outcomes, standardised mean difference, and 95% CIs were calculated. Statistical heterogeneity and the extent of inconsistency between the study findings were investigated and assessed using the Higgins I^2 and the variance estimate, τ^2.

We also explored the feasibility of quantifying the relationship between the mode of delivery, BCT and theory-congruent clusters, and treatment effects, through pairwise and indirect comparisons of the components of the interventions (according to the proposed coding described in *Classification of Behavioural change techniques*). Indirect comparisons require any two treatments to have a common comparator or a link through a chain of comparisons. In other words, a chosen baseline treatment can be indirectly compared with another treatment provided there is at least one connecting comparison. For example, consider three treatments labelled A, B and C. If we let d_{AC} denote the direct comparison of

treatment A with treatment C, and d_{BC} denote the direct comparison of treatment B with treatment C, then a crude estimate for the relative (indirect) comparison of treatment A with treatment B could be $d_{AB} = d_{AC} - d_{BC}$. Therefore, given the known direct evidence of the effect of treatments A and B compared with treatment C, we can indirectly estimate the effect of treatment A compared with treatment B when treatment C is the connecting treatment. Subsequently, a Bayesian random-effects network meta-analysis can be performed based on minimally informative prior distributions.[94,95]

However, similar to pairwise meta-analysis, indirect comparisons are feasible only when the studies are sufficiently homogeneous; the individual trials need to be comparable in terms of effect modifiers. In particular, indirect comparisons require a common connecting treatment. Furthermore, if 'usual care' were to be selected as the common comparator, the definitions of usual care across individual studies need to be sufficiently similar to be considered a common comparator, with an assumption of similarity or transitivity. Another key assumption to ensure validity of indirect comparison is consistency of treatment effects between direct and indirect evidence. When estimates from direct and indirect evidence vary substantially beyond sampling error, the results are unreliable. Therefore, indirect treatment comparisons should be carried out only when the data comply to the fundamental assumption of consistency and transitivity.[94,95]

All analyses were performed using Stata version 11 (StataCorp LP, College Station, TX, USA).

Chapter 3 Systematic review results

Included studies

The searches identified 3500 records (see *Appendix 3* for details of database sources and references obtained). After duplicates were removed, we reviewed 2571 records (*Figure 1*). Following reviewing of titles, abstracts and full texts, 11 studies meeting the inclusion criteria were included in the review.[96–106]

Number and type of studies excluded

A total of 92 full texts were excluded, as they did not meet the inclusion criteria. The reasons for each decision are given in *Appendix 3*. Articles were excluded for not being a RCT or other suitable study, as specified in our inclusion criteria;[107–136] not having the sufficient percentage of MSM in the study population;[137–145] not including a sufficient percentage of HIV-negative participants;[146–156] or not being an individually focused intervention, instead focusing on groups or structural factors.[157–167] Other reasons for exclusion, such as interventions not being brief, reporting a pilot trial, reporting non-HIV-specific data (e.g. if only alcohol-related outcomes were provided in a study assessing alcohol as well as HIV risk-related

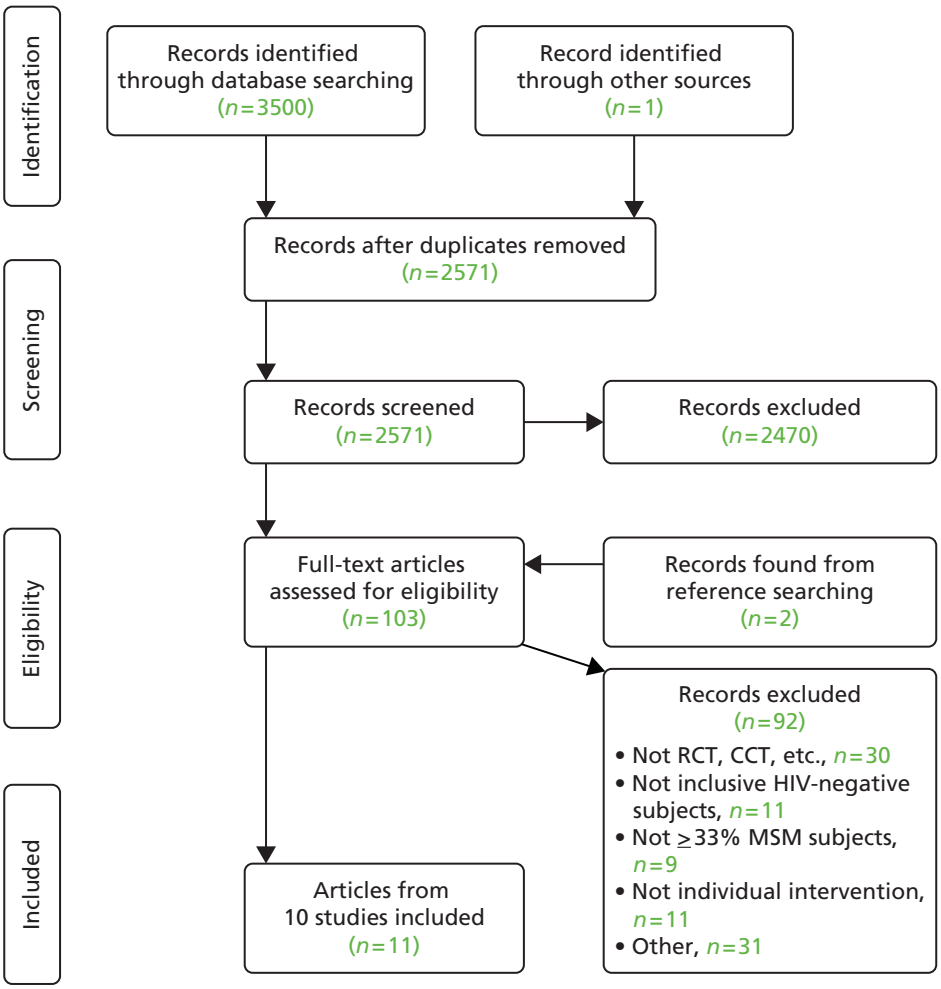

FIGURE 1 The PRISMA flow chart for study selection. CCT, controlled clinical trial.

behaviours) or data were unobtainable despite our attempts to gain information from authors, were captured in our 'other' category.[99,168–197]

Ten RCTs, reported in 11 studies, met the inclusion criteria and were included in the final review.[96–106] A summary of the characteristics of the included studies are shown in *Table 2*. All studies were conducted in the USA with the exception of one study, which was conducted in China.[103] These studies evaluated the efficacy of a number of online and face-to-face interventions in the reduction of HIV risk-related behaviour.

Recruitment methods and eligibility criteria

Table 2 shows that the participants across the trials were recruited through a variety of sources. These include recruitment of those who attended clinics for testing,[99–101] and recruitment via community outreach,[98] at gay bars[103,105] and through distribution of advertising material and fliers.[102,105] A number of studies, in particular those evaluating online interventions, recruited participants online using banner advertisements on relevant websites.[96,97,102–104] One study also used respondent-driven sampling after initially recruiting at relevant commercial gay venues.[103]

Eligibility criteria were similar across all studies; all participants were MSM who engaged in HIV risk-related sexual activity within a specified time period. However, the definition of HIV infection risk and the associated time period varied. The number of individuals randomised across the trials ranged from 143 to 3029. The mean age of the participants was reported in five trials; the ages ranged from 16 years to > 61 years. Three trials specifically targeted 'young' adult MSM: 18–24 years,[97] 18–39 years[96] and 18–29 years.[105] The majority of participants across the trials were self-identified as 'white' or 'Caucasian'. In one trial, a separate analysis on the subgroup of 'men of colour' was undertaken.[99] The trial conducted in China[103] did not report ethnicity within the Chinese population. Most studies recruited only HIV-negative participants. In one study, HIV status for 16% of the participants was unknown.[96] In another study, 17% of participants were HIV positive and 8% were of unknown HIV status.[104] Similarly, one study included 21% HIV-positive and 9% HIV-unknown status participants.[106] Socioeconomic status was not reported explicitly in any study and other markers of socioeconomic status are inconsistently reported (income, educational attainment and employment status). However, most studies note that their samples tend to over-represent men with higher socioeconomic status. One notable exception is Eaton *et al.*,[102] who highlight the relatively high numbers of men with low income and unemployment within their study (specific details of educational attainment are not reported).

Outcome measures

All studies sought to minimise the risk of HIV transmission. As *Table 2* shows, within the studies multiple outcomes are described, and discernible hierarchies of outcomes are often unclear. A priori primary outcomes are rarely listed. Carpenter *et al.*,[96] for example, do not detail any primary outcomes per se, Parsons *et al.*[105] only detail provide concerning 'outcomes of interest' and Eaton *et al.*[102] provide multiple outcomes. Similarly, Picciano *et al.*[106] do not clearly state primary outcomes. All other studies provide some detail of primary outcomes; some explicitly refer to secondary outcomes.

Primary outcomes are as follows: incidence of UAI at a 3-month follow-up (inferred);[96] change in counts of risky sexual behaviour over 3 months;[97] number of UAI events; number of UAI partners and number of UAI events with three most recent non-primary partners;[98] UAI in the preceding 90 days with a man who is not the primary partner and who is of unknown or discordant HIV status;[101] change in number of episodes of UAI within a 90-day period;[100] change in number of episodes of UAI with non-primary non-concordant male partners in previous 90 days;[99] and number of unprotected anal sex acts with HIV-positive/unknown status partners (inferred).[102] Hao *et al.*[103] report a range of primary outcomes, including episodes of UAI with any male sex partners in previous 6 months; episodes of UAI with regular male sex partners in

TABLE 2 Overview of studies

Author (year of publication); country of study	Purpose (aim and objectives)	Nature of intervention(s)	Primary outcome(s) measures	Secondary outcome(s) and measures	Control intervention	Recruitment methods	Eligibility criteria	Exclusion criteria
Carpenter *et al.* (2010);[96] USA	To investigate the efficacy of a web-based skills training and motivational intervention to reduce the risk of HIV infection and other STIs by increasing knowledge of risk factors, providing skills training for safer behaviour and increasing motivation for behaviour change	Single tutorial of multimedia intervention to increase knowledge of risk factors regarding HIV and STIs	Self-reported sexual behaviour (incidence of UAI) at a 3-month follow-up	Satisfaction with intervention as rating of intervention's ease of use, attractiveness and enjoyability	Online stress reduction training program (eTranquility) customised for a younger MSM population	Banner advertisements posted on same-sex community websites; profiles of study posted on minority websites	MSM who had unprotected sex with a man within last 3 months; had access to relevant computing and internet equipment; were willing to provide an active e-mail address; were able to read and understand English; resided in the USA; had not participated in another psychosocial HIV intervention in past year	None stated
Christensen *et al.* (2013);[97] USA	To test if a downloadable simulation video game designed to reduce MSM's sexual shame, does so and if that reduction predicts HIV infection risk reduction; to test if at baseline, MSM's reported past UAI is related to shame; MSM's exposure to SOLVE compared with a waiting list control condition reduces MSM's shame; and shame reduction mediates the link between waiting list control condition and UAI risk reduction	Online SOLVE immersion video game	Efficacy of SOLVE (vs. a waiting list control condition) in reducing shame and directly or indirectly (via shame reduction) in reducing UAI over 3 months measured as change in the counts of risky sexual behaviour	Change in shame from baseline to immediately after testing, as measured by five items from existing subscale of the Positive and Negative Affect Schedule	Waiting list control: same baseline and immediately after testing, measures as SOLVE treatment condition but did not play game	Clickable banner advertisements on websites frequented by target population	Self-identification as black/African American, Hispanic/Latino or white/Caucasian. Self-reported: 1. had a prior HIV-negative test result 2. lived in the USA 3. were between 18 and 24 years old 4. engaged in UAI with a non-primary male partner during the 3-month period prior to enrolment	1. Participation in prior SOLVE studies; non-corrected vision/hearing impairment; history of injecting non-prescribed drugs 2. Post allocation: not completing baseline measures. In SOLVE condition: unwilling or unable to download game and/or unable to play at least one of two game levels

continued

TABLE 2 Overview of studies (*continued*)

Author (year of publication); country of study	Purpose (aim and objectives)	Nature of intervention(s)	Primary outcome(s) measures	Secondary outcome(s) and measures	Control intervention	Recruitment methods	Eligibility criteria	Exclusion criteria
Coffin *et al.* (2014);[98] USA	To determine if people randomised to receive adapted PCC will report greater reductions in UAI behaviour compared with people who do not receive PCC	Adapted PCC to help address self-justifications employed in high-risk sexual behaviour settings	Efficacy of PCC (vs. no PCC) in reducing UAI behaviour as: 1. change in total UAI events during previous 3 months 2. change in total UAI partners during previous 3 months 3. change in total episodes with three most recent non-primary partners over previous 3 months	• Number of serodiscordant UAI events over previous 3 months with non-primary partners • Number of insertive UAI events over previous 3 months • Number of receptive UAI events over previous 3 months • Number of condom-protected AI events over previous 3 months (measured at baseline and at 3 and 6 months)	Standard HIV infection testing with information only	Street outreach at community venues and community organisations for African American, Latino, Asian and Pacific Islander MSM	• Reported UAI with another man while under influence of one/combination of listed substances within 2 hour before/during sex within previous 6 months • Identified as male • HIV negative or not known by self-report • Willing and able to participate in intervention regarding episodic substance use and sexual risk-related behaviour • Not in substance use/self-help/HIV infection prevention programmes or receiving prophylaxis • Had not injected any substances in previous 6 months • Aged ≥ 18 years • Living/staying in San Francisco Bay Area for duration of study • Could speak, read and understand English	• Reported UAI during previous 6 months with only one primary partner • Weekly or more use of targeted substances in previous 3 months • For alcohol, more than the average three alcoholic drinks daily or binge drinking more than twice weekly

Author (year of publication); country of study	Purpose (aim and objectives)	Nature of intervention(s)	Primary outcome(s) measures	Secondary outcome(s) and measures	Control intervention	Recruitment methods	Eligibility criteria	Exclusion criteria
Dilley *et al.* (2011);[99] USA	To conduct a secondary analysis to measure the efficacy of PCC separately for men of colour and for white men who participated in the authors' 2007 study[100]	Adapted PCC to help address self-justifications employed in high-risk sexual behaviour settings	Efficacy of a single specialised pre-test counselling session in reducing HIV infection risk-related behaviour in HIV-negative men, as measured in the change in the number of episodes of UAI with non-primary non-concordant male partners in the previous 90 days	Client's satisfaction with the counselling session and his attitude about the utility of the session, as measured by the Client Satisfaction Survey	Standard HIV infection testing with counselling/ information only regarding CDC's guidelines (usual care)	Men recruited when they telephoned to set up an appointment for HIV infection testing at counselling and testing site or presented at a drop-in clinic	HIV-negative MSM reporting a history of UAI within the previous 12 months with another man whose serostatus was unknown to participant or was known to be HIV positive	Not reported
Dilley *et al.* (2007);[100] USA	To test efficacy and acceptability of a single-session PCC intervention delivered by paraprofessionals during HIV voluntary counselling and testing to determine whether or not: • paraprofessional counsellors could learn/conduct PCC intervention according to protocol • intervention would remain effective in reducing future UAI episodes when provided by paraprofessionals and be more effective than usual care • client satisfaction would be at least as high in intervention compared with control treatment	Adapted PCC to help address self-justifications employed in high-risk sexual behaviour settings	Efficacy of a single specialised pre-test counselling session in reducing HIV infection risk-related behaviour in HIV-negative MSM, as measured in the change in the number of episodes of UAI across 90 days	Acceptability as assessed by a standardised Client Satisfaction Survey	Standard HIV infection testing with counselling/ information only regarding CDC's guidelines (usual care)	MSM recruited when telephoning to set up an appointment for HIV infection testing at counselling and testing site or presenting for anonymous testing at a drop-in clinic	HIV-negative MSM reporting a history of UAI within the previous 12 months with another man whose serostatus was unknown to participant or was known to be HIV positive	People who reported non-prescription intravenous drug use during the prior 12 months

continued

TABLE 2 Overview of studies (*continued*)

Author (year of publication); country of study	Purpose (aim and objectives)	Nature of intervention(s)	Primary outcome(s) measures	Secondary outcome(s) and measures	Control intervention	Recruitment methods	Eligibility criteria	Exclusion criteria
Dilley *et al.* (2002);[101] USA	To assess whether or not one counselling intervention session focusing on self-justifications at most recent UAI is effective in reducing future high-risk behaviours among HIV-negative men	Adapted PCC to help address self-justifications employed in high-risk sexual behaviour settings. Compared with usual care and 90-day sexual diary or PCC and usual care and 90-day sexual diary or usual care only (control)	Efficacy of a single specialised pre-test counselling session in reducing HIV infection risk-related behaviour in HIV-negative repeat testing MSM, as measured in the change in the number of episodes of UAI	None reported	Standard HIV infection testing with counselling/ information only regarding CDC's guidelines (usual care)	MSM screened when telephoning to set up an appointment for anonymous HIV antibody testing at an anonymous HIV testing clinic	HIV-negative MSM reporting a history of UAI within the previous 12 months with another man whose serostatus was unknown to participant or was known to be HIV positive	People who reported non-prescription intravenous drug use during the prior 12 months
Eaton *et al.* (2011);[102] USA	To test a novel, brief, one-on-one intervention, based on informed decision-making and delivered by peer counsellors, designed to address the limitations of serosorting (e.g. risk for HIV transmission) among MSM	Novel brief one-to-one interventions based on informed decision-making using graphic novel, designed to address limitations of serosorting compared with usual care	Efficacy of intervention in promoting risk reduction for HIV infection measured as: • changes in condom use self-efficacy • risk perceptions • total number of male sexual partners • number of HIV-negative partners • number of HIV-positive/unknown status partners • number of UAI acts with HIV-negative partners • number of UAI acts with HIV-positive/ unknown status partners	None reported	Time-matched, standard of care control intervention (standard, HIV infection risk reduction counselling regarding CDC's guidelines)	Flyers at HIV infection testing sites, treatment centres and gay-identified venues; advertisements in local gay newspapers and on an internet classifieds website; in-field recruitment methods	• HIV-negative male or transgendered • Aged ≥ 18 years • To report having had two or more male unprotected anal sex partners in the preceding 6 months	None additional

Author (year of publication); country of study	Purpose (aim and objectives)	Nature of intervention(s)	Primary outcome(s) measures	Secondary outcome(s) and measures	Control intervention	Recruitment methods	Eligibility criteria	Exclusion criteria
Hao *et al.* (2012);[103] China	To test the relative efficacy of EVCT vs. SVCT in reducing UAI among MSM in China; to evaluate the intervention's relative efficacy on reducing HIV and syphilis incidence	EVCT which consists of: • a video narrated by HIV-positive man to encourage safer sex by influencing behaviour and perceptions • counselling to assess stage of change and increase motivation to use condoms • gift as reminder for safer sex	Reduction of incidence of UAI as measured by: • episodes of UAI with any male sex partners in previous 6 months • episodes of UAI with regular male sex partners in previous 6 months • episodes of UAI with casual male sex partners in previous 6 months	Change in HIV and syphilis incidence	SVCT	Respondent-driven sampling: • initial recruitment from public venues, internet and peer referral who recruited others • process repeated in waves until target sample size achieved	HIV-negative male aged ≥ 18 years who self-reported as having had anal sex with men in the last 12 months	Those who showed a positive result in the rapid test for the HIV antibody
Hirshfield *et al.* (2012);[104] USA	To assess feasibility and efficacy of implementing a large-scale single-session online intervention, using HIV infection prevention videos or a HIV infection prevention web page vs. a no-content control among sexually active MSM	Video and web-based behavioural interventions. • Videos: dramatic – 'The Morning After' about three gay friends addressing sexual risk reduction within the context of alcohol use designed to promote critical thinking about HIV disclosure, HIV infection testing and condom use • Documentary: 'Talking About HIV' designed to promote critical thinking about HIV disclosure, HIV infection testing and condom use, with the subcontext of drug use	Efficacy of intervention on reducing HIV infection risk as changes in: • HIV infection testing • serostatus disclosure • UAI incidence at 60-day follow-up	[Protocol only] drug and/or alcohol use before sex and depressive and/or anxiety symptomatology (past 2 weeks) at 60 days	Link to HIV infection prevention web page: standard text-based web page (www.CDC.gov) that describes HIV infection prevention among MSM and provides links to prevention information and resources following completion of brief behavioural survey (to measure intentions) immediately after consent	Banner advertisement placed on four gay-oriented sexual networking websites for American men; (later) e-mails via one website's internal system to all US members (i.e. list-based sampling frame)	• Who identify as a man • Aged ≥ 18 years • Reside in the USA • Provides an e-mail address • Reports oral or anal sex with current male partner and oral, anal or vaginal sex with at least one new partner (male or female) in previous 60 days • Has the ability to read and respond in English	Women and transgender people

continued

TABLE 2 Overview of studies (*continued*)

Author (year of publication); country of study	Purpose (aim and objectives)	Nature of intervention(s)	Primary outcome(s) measures	Secondary outcome(s) and measures	Control intervention	Recruitment methods	Eligibility criteria	Exclusion criteria
Parsons *et al.* (2014);[105] USA	To test brief MI intervention to reduce both risky sex and drug use among HIV-negative young gay and bisexual men	MI	To reduce UAI with a casual partner (overall and under the influence of drugs/alcohol) and the number of days of drug use – these were collected using 30-day timeline follow back	Critical life events were reviewed retrospectively to prompt recall of daily sex and drug use	Content matched educational session to reduce both risky sex and drug use	• Active recruitment (71%) using palm pilots in a variety of venues catering to young gay and bisexual men (bars, clubs, sex venues, streets in predominantly gay neighbourhoods, LGBT community events) • Passive recruitment (12%) using tear-off flyers and project recruitment cards left on premises, advertisements placed in gay and non-gay publications • Internet recruitment (9%) using chat rooms and banner advertisements. Friend referrals (8%)	• Aged 18–29 years • Reported as having a HIV-negative or unknown status • At least 5 days of drug use (specifically cocaine, methamphetamine, gamma hydroxybutyrate, ecstasy, ketamine or poppers) • At least one incident of UAI with a high-risk male partner (HIV-positive or unknown status main partner or casual partner of any HIV status) in previous 90 days	• Main partner that was HIV positive • Participants who reported having sex only with main partner 30 days prior to baseline
Picciano *et al.* (2007);[106] USA	To test the efficacy of a brief theory-based counselling intervention based on MET principles and delivered entirely by telephone for promoting safer sex practices for MSM	Telephone-delivered MET	• % participants reporting monogamy • % participants reporting negotiated safety relationships • % participants reporting using condoms for all anal sex occasions • % participants reporting abstaining from anal sex	Efficacy of intervention in promoting safer sex practices among at-risk MSM as behavioural count data (regarding IMB constructs): • HIV knowledge and condom use • Motivational indicators • Behavioural skills (enactment) collected at the baseline and 4-, 7- and 10-month follow-ups	Knowledge check: brief HIV education counselling (delayed counselling control condition)	• By outreach workers in gay-identified bars • Paid print advertisement in the local alternative and gay press	• Aged ≥ 16 years • Reporting at least one episode of UAI with a male partner in previous 90 days • Not receiving counselling services to become sexually safer elsewhere	In a mutually monogamous or negotiated safety relationship that included requirements that person and main partner had tested for HIV twice, at least 3 months apart, while maintaining their agreement

AI, anal intercourse; EVCT, enhanced voluntary counselling and testing; IMB, information, motivation and behaviour skills model; LGBT, lesbian, gay, bisexual and transgender; PCC, personal cognitive counselling; SOLVE, Socially Optimised Learning in Virtual Environments; SVCT, standard voluntary counselling and testing; UC, usual care.

previous 6 months; and episodes of UAI with casual male sex partners in previous 6 months.[103] Hirshfield *et al.*[104] utilised HIV infection testing, serostatus disclosure and UAI incidence at 60-day follow-up.[104] Parsons *et al.*[105] utilised UAI with a casual partner (overall and under the influence of drugs/alcohol) and number of days of drug use (inferred). It can be inferred that Picciano *et al.*[106] utilised a range of primary outcomes including percentage of participants reporting monogamy; percentage of participants reporting negotiated safety relationships; percentage of participants reporting using condoms for all anal sex occasions; and percentage of participants reporting abstaining from anal sex.[106]

Therefore, UAI was the most common outcome utilised; however, definitions also differed among studies. These differences related to addressing the more complex aspects of measuring HIV risk, for example sex role within unprotected sex or partner type. Some studies incorporated aspects of the relationship context of unprotected sex; for example Dilley *et al.*[99–101] specifically measured the number of UAI sex episodes with non-primary non-concordant male partners in the previous 90 days. Similarly, Hao *et al.*[103] differentiated between UAI with regular and casual male sex partners. Carpenter *et al.*[96] and Eaton *et al.*[102] assessed HIV status of sexual partners to further differentiate the context of UAI.

In terms of secondary outcomes, it can be inferred that Christensen *et al.*[97] address sex shame from baseline to immediately after testing. Hao *et al.*[103] report change in HIV and syphilis incidence, whereas Eaton *et al.*[102] reported condom use self-efficacy and HIV risk perceptions. Eaton collected data on alcohol and substance use among participants using the Drug Abuse Screening Test and Alcohol Use Disorders Identification Test measures. Picciano *et al.*[106] also collected data on drug use using the Drug Abuse Screening Test. Dilley *et al.*[100] collected data on incidence of drug use using the Addiction Severity Index.

The follow-up periods ranged from 1 week to 12 months across the trials: 1 week,[106] 1 month,[102] 2 months,[104] 3 months,[96–102,105] 4 months,[106] 6 months,[99–101,103,105] 7 months,[106] 9 months,[105] 10 months[106] and 12 months.[99–101,105] Incentives were provided in all studies, with the exception of Hirshfield *et al.*[104]

No measures relating to economic aspects of the interventions were described.

Nature of interventions and comparators

Table 3 shows that the interventions evaluated varied considerably in their overall and specific content, and in relation to the ways that distinct intervention components were sequentially delivered. Many were, broadly speaking, brief counselling-based interventions, often incorporating major elements of MI.[96,103] MET was evaluated in one study[106] and represents an adapted version of MI. Personal cognitive counselling (PCC) was used in several studies and combined techniques drawn from MI.[98–101] PCC uses structured questions to encourage clients to scrutinise and change their 'self-justifications' (e.g. thoughts, attitudes or beliefs), which are understood to facilitate their engagement in high-risk sexual behaviours.

Five studies evaluated interventions based on novel interactive visual and/or multimedia components.[96,97,102–104] These include the use of a multimedia presentation using simulated peers;[96] intervention based on 'Socially Optimised Learning in Virtual Environments',[97] an interactive game incorporating avatars to engage in decision-making and rehearse behavioural skills in a number of virtual scenarios involving sexual decision-making situations and a specially designed graphic novel which was intended to facilitate sexual decision-making.[102] The graphic novel visually depicted a narrative of a man and his journey to seroconversion. Video-based components were also included in two studies evaluating multicomponent interventions.[103,104]

In the majority of the studies, behavioural change interventions were compared with a 'usual care' intervention. These were usually brief standard counselling-based interventions based on local CDC guidelines.[99–103] Other studies used knowledge or information-based interventions;[98,104,106] for instance, Coffin *et al.*[98] delivered HIV infection testing followed by information on HIV transmission and testing; and Carpenter *et al.*[96] delivered a stress reduction intervention. One study used a waiting list control.[97]

TABLE 3 Modes of intervention delivery

Author (year of publication)	Intervention	Intervention delivery mode (e.g. online, face to face, telephone)	Intervention delivery by whom/what (e.g. peers, counsellors, clinicians, researchers, avatars)	Intervention setting(s)	Frequency of intervention sessions	Duration and intensity of individual interventions	Follow-up period(s)[a]
Carpenter *et al.* (2010)[96]	MI based	Online	Multimedia (seven modules of online interactive exercises; multimedia presentations audio clips of simulated peers)	Personal via internet (various cities and regions in the USA)	Single tutorial: not required to complete at one sitting, but required to complete within 1 week (also reviewed at follow-up without restriction)	Total time: approximately 1.5–2 hours	3-month follow-up assessment and review of tutorial without restriction
Christensen *et al.* (2013)[97]	SOLVE	Online	Online interactive virtual environments; virtual peers/mentors, guides and partners; online assessments	Personal via internet (online or downloaded to own computer), authors' recommended privacy (USA)	Online/downloaded immersive two-level video game	No information on time needed to play game or number of times played	3-month UAI assessment
Coffin *et al.* (2014)[98]	PCC	Face to face (one to one)	Counsellors trained and certified in HIV infection testing and counselling who attended refresher courses every 6–12 months	Clinic setting: San Francisco Department of Public Health clinic setting, CA, USA (scheduled appointment, private counselling); self-completion ACASI-based questionnaire (and standard HIV infection testing and counselling)	1. Single PCC session 2. At 3-month follow-up, one of three types of tailored booster counselling session: i. PCC and self-justification elicitation instrument ii. Counselling regarding HIV status and risk iii. General counselling	30–50 minutes. Unclear time of booster sessions	3- and 6-month follow-up
Dilley *et al.* (2011)[99]	PCC	Face to face (one to one)	Trained paraprofessional counsellors (certified HIV infection test counsellors)	Clinic setting: publicly funded HIV counselling and testing venues in San Francisco, CA, USA (San Francisco's largest counselling and testing site or presented at a drop-in clinic)	Single PCC intervention and UC	Total: average 50-minute counsellor contact given after HIV infection test results (UC = 30 minutes)	6- and 12-month follow-up ACASI

Author (year of publication)	Intervention	Intervention delivery mode (e.g. online, face to face, telephone)	Intervention delivery by whom/what (e.g. peers, counsellors, clinicians, researchers, avatars)	Intervention setting(s)	Frequency of intervention sessions	Duration and intensity of individual interventions	Follow-up period(s)[a]
Dilley *et al.* (2007)[100]	PCC	Face to face (one to one)	Trained paraprofessional counsellors (certified HIV test counsellors)	Clinic setting: publicly funded HIV counselling and testing venues in San Francisco, CA, USA (San Francisco's largest counselling and testing site or presented at a drop-in clinic)	Single PCC intervention and UC	Total: average 50-minute counsellor contact given after HIV infection test results (UC = 30 minutes)	6- and 12-month follow-up
Dilley *et al.* (2002)[101]	PCC	Face to face (one to one)	Licensed mental health professionals (for PCC conditions B1 and B2 arms)	Clinic setting: anonymous HIV counselling and testing clinic in San Francisco, CA, USA	• A1: single-session UC only • A2: single-session UC and 90-day sexual diary • B1: single-session PCC after completion of self-justifications questionnaire (and UC) • B2: single-session PCC after completion of self-justifications questionnaire (and UC and 90-day sexual diary)	PCC counselling approximately 1 hour (UC = 30 minutes)	6- and 12-month follow-up evaluations
Eaton *et al.* (2011)[102]	Counselling based on graphic novel	Face to face (one to one)	Peer counsellors discussing graphic novel graph-based prompt	Research site: community-based research site in downtown area of Atlanta, GA, USA	Single session	Approximately 40 minutes	1- and 3-month follow-up assessments
Hao *et al.* (2012)[103]	Enhanced VCT including audio–visual presentation, counselling and visual cue	Face to face (one to one and video)	Clinicians trained in VCT	Clinic setting: VCT clinic of Jiangsu Provincial Centre for Disease Control and Prevention, Nanjing, China	Single session: including video, counselling and cloth bracelet gift	Video (6 minutes) and counselling (10 minutes). Total approximately 16 minutes	6-month follow-up assessment and evaluation

continued

TABLE 3 Modes of intervention delivery (*continued*)

Author (year of publication)	Intervention	Intervention delivery mode (e.g. online, face to face, telephone)	Intervention delivery by whom/what (e.g. peers, counsellors, clinicians, researchers, avatars)	Intervention setting(s)	Frequency of intervention sessions	Duration and intensity of individual interventions	Follow-up period(s)[a]
Hirshfield *et al.* (2012)[104]	Video and web-based behavioural interventions	Online (video and web pages)	Participants assigned to five conditions (four and a control): 1. Dramatic video 2. Documentary video 3. Both dramatic and documentary videos 4. Prevention web page 5. Control (i.e. received no intervention content)	Personal via internet (USA)	Single session	1. Approximately 9 minutes 2. Approximately 5 minutes 3. Approximately 14 minutes 4. Unknown	60-day follow-up survey
Parsons *et al.* (2014)[105]	MI	Face to face (one to one)	Trained therapists (control condition educators also trained)	Research site: (presumably in NY, USA, where participants were recruited)	Four sessions	Duration of each session unclear (although at least 20 minutes as 20-minute extracts were analysed for treatment fidelity analysis); also included pre-intervention ACASI and post-intervention completion of timeline follow-back calendar of substance use and sexual behaviours for past 30 days	3-, 4-, 9- and 12-month assessments
Picciano *et al.* (2007)[106]	MET	Telephone (one to one)	Trained counsellor	Personal via telephone (Seattle, WA, and Portland, OR, USA)	Up to three MET sessions. First session to be completed within 30 days of baseline interview, remaining session(s) within 42 days of baseline (i.e. maximum 3 × 90-minute MET sessions)	Up to 90 minutes per session. Up to 4.5 hours plus CATI sessions: 5 × 45 minutes = 3.75 hours. Total: maximum 8.25 hours	1-week post-counselling intervention and at 4, 7, and 10 months from study enrolment

ACASI, audio computer-assisted self-interview; CATI, computer-aided telephone interview; SOLVE, Socially Optimised Learning in Virtual Environments; UC, usual care; VCT, voluntary counselling and testing.

a Follow-up period(s) must assess at least once from baseline.

Apart from the three online interventions, most of the interventions were delivered in a clinical setting[98–101,103] and two were delivered at a research site.[102,105] Most interventions were delivered as single/one-off sessions except Parsons *et al.*[105] and Picciano *et al.*[106] Dilley *et al.*[101] included a diary intervention in two of the study arms. The duration of each session ranged from 16 minutes[103] to a maximum of 8 hours and 25 minutes delivered over a number of sessions[106] (although it should be noted that duration of actual intervention delivery was not recorded).

Proximity to testing

Table 4 describes how the studies included within the systematic review are patterned according to the HIV infection testing process.

Excluding Hirshfield *et al.*[104] and Picciano *et al.*,[106] all interventions can be seen as utilising HIV-negative status. Dilley *et al.*[101] delivered their intervention after testing but before the result was available. Coffin *et al.*,[98] Dilley *et al.*,[100] and Hao *et al.*[103] all delivered their interventions after the patient received a negative test result (thus encompassing any effects of the testing process itself and providing the most accurate HIV-negative status and potential HIV-negative identity).

TABLE 4 Proximity to testing

Author (year of publication)	Intervention offered immediately after receipt of a HIV-negative test result	Intervention offered immediately post-HIV infection testing process in the absence of a results being given	Intervention offered to those who have tested HIV negative within the 12 months preceding the intervention	Intervention offered to those who have tested previously at some point and have received a HIV-negative test result	Intervention offered irrespective of status, but within the study HIV status is recorded
Carpenter *et al.* (2010)[96]				✗	
Christensen *et al.* (2013)[97]				✗	
Coffin *et al.* (2014)[98]	✗				
Dilley *et al.* (2007)[100]	✗				
Dilley *et al.* (2002)[101]		✗			
Eaton *et al.* (2011)[102]				✗	
Hao *et al.* (2012)[103]	✗				
Hirshfield *et al.* (2012)[104]					✗
Parsons *et al.* (2014)[105]				✗	
Picciano *et al.* (2007)[106]					✗

Behaviour change techniques utilised within interventions and controls

The range of BCTs utilised in both interventions and controls is summarised in *Table 5*. Across the selected studies, at least one BCT from 15 of the 16 groups of BCTs were included. Only BCTs associated with grouping 14, 'scheduled consequences', were not represented in the data set. In total, 32 BCTs out of a possible 93 were utilised in the selected studies. The intervention used in Hirshfield *et al.*[104] used the fewest BCTs ($n = 4$), while the one-to-one counselling-based interventions in Dilley *et al.*[100,101] utilised the most BCTs ($n = 11$ each). Examining the BCTs used across interventions and controls, the most commonly used BCTs were 'social support (unspecified)'[98–106] and 'information about health consequences', which were present across eight studies.[96,97,99–104,106] Other BCTs that were relatively common were 'problem-solving'[96,98–102,105] and 'pros and cons'.[96,97,102,103,105,106]

The control interventions included fewer BCTs overall and, hence, fewer groupings were represented. BCTs associated with the groupings 'associations', 'repetition and substitution', 'comparison of outcomes, 'rewards and threat', 'scheduled consequences' and 'covert learning', were not represented. In total, 14 out of a possible 93 BCTs were used in the control interventions across all the included studies. Note that Christensen *et al.*[97] used a waiting list control. Many of the control interventions were described as 'usual care' brief counselling-based interventions and this was reflected in the BCT coding. The most common BCTs used in the controls were 'information about health consequences' and 'social support (unspecified)', which were present in eight and seven studies, respectively. BCTs used in active control groups, such as usual care, may well be important active ingredients within interventions.

TABLE 5 Behaviour change techniques: definitions and illustrative examples

BCT	BCT definition	Example of unique BCTs from primary study
1.1 Goal-setting (behaviour)	Set or agree a goal defined in terms of the behaviour to be achieved	*. . . printable goal-setting exercise* *Carpenter* et al.[96]
1.2 Problem-solving	Analyse factors influencing the behaviour and generate or select strategies that include overcoming barriers and/or increasing facilitators	*. . . they reviewed the occasions in which they had unwittingly put themselves at risk for HIV in the past and discussed what they could do differently in the future to reduce their risk* *Eaton* et al.[102]
1.3 Goal-setting (outcome)	Set or agree a goal defined in terms of a positive outcome of wanted behaviour	*The counselor helped the participant to confront these ideas [self-justifications] and work toward a plan to address these in the future* *Dilley* et al.[100]
1.4 Action planning	Prompt detailed planning of performance of the behaviour (must include at least one of context, frequency, duration and intensity). Context may be environmental (physical or social) or internal (physical, emotional or cognitive)	*An action plan was made by participants* *Picciano* et al.[106]
1.5 Review behaviour goal(s)	Review behaviour goal(s) jointly with the person and consider modifying goal(s) or behaviour change strategy in the light of achievement. This may lead to resetting the same goal, a small change in that goal or setting a new goal instead of (or in addition to) the first, or no change	*Session 4 . . . included a final review and revision of the participants' goals and change plan* *Parsons* et al.[105]

TABLE 5 Behaviour change techniques: definitions and illustrative examples (*continued*)

BCT	BCT definition	Example of unique BCTs from primary study
2.1. Monitoring of behaviour by others without feedback	Observe or record behaviour with the person's knowledge as part of a behaviour change strategy	*The standard pre-test counselling included . . . assessment of risk behaviours practiced by the participant* *Hao* et al.[103]
2.2. Feedback on behaviour	Monitor and provide feedback on performance of the behaviour	*Components include feedback on personal behaviour . . .* *Picciano* et al.[106]
2.3. Self-monitoring of behaviour	Establish a method for the person to monitor and record their behaviour(s) as part of a behaviour change strategy	*Participants . . . were asked to keep a 90-day sexual diary identifying the kinds of sex engaged in, condom use . . .* *Dilley* et al.[101]
3.1. Social support (unspecified)	Advise on, arrange or provide social support (e.g. from friends, relatives, colleagues,' buddies' or staff) or non-contingent praise or reward for performance of the behaviour	*. . . included a review of community resources and support services available, and an individualised referral list . . .* *Parsons* et al.[105]
3.3. Social support (emotional)	Advise on, arrange, or provide emotional social support for performing the behaviour	*The delivery of motivational interviewing* *Carpenter* et al.[96]
4.1. Instruction on how to perform the behaviour	Advise or agree on how to perform the behaviour	*. . . providing skills training for safer behaviour . . .* *Carpenter* et al.[96]
4.2. Information about antecedents	Provide information about antecedents (e.g. social and environmental situations and events, emotions or cognitions) that reliably predict performance of the behaviour	*. . . by increasing knowledge of risk factors e.g. drug and alcohol use* *Carpenter* et al.[96]
5.1. Information about health consequences	Provide information about emotional consequences of performing the behaviour	*. . . reminding participants about the risk for HIV transmission via unprotected sex . . .* *Hao* et al.[103]
5.3. Information about social and environmental consequences	Provide information about social and environmental consequences of performing the behaviour	*. . . behavior is evaluated and linked to real-life consequences . . .* *Christensen* et al.[96]
6.1. Demonstration of the behaviour	Provide an observable sample of the performance of the behaviour, directly in person or indirectly (e.g. via film, pictures) for the person to aspire to or imitate	*. . . alternatives for unsafe sex were presented through . . . audio narratives* *Carpenter* et al.[96]
6.2. Social comparison	Draw attention to others' performance to explicitly elicit comparisons	*Then participants were asked to create their own sexual network diagram by providing information about their sexual partners and acts during the preceding 6 months. Participants diagrams were then compared with the characters diagram, thereby allowing participants to observe how their behaviours related to those of an evidence-based character who tests positive for HIV* *Eaton* et al.[102]
7.1. Prompts/cues	Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behaviour. The prompt or cue would normally occur at the time or place of performance	*. . . receiving a cloth bracelet as a reminder for safe sex* *Hao* et al.[103]
8.1. Behavioural practice/rehearsal	Prompt practice or rehearsal of the performance of the behaviour one or more times in a context or at a time when the performance may not be necessary, in order to increase habit and skill	*. . . gains experience initiating a conversation about safe sex, negotiating condom use and refusing sex if a condom is unavailable* *Christensen* et al.[97]

continued

TABLE 5 Behaviour change techniques: definitions and illustrative examples (*continued*)

BCT	BCT definition	Example of unique BCTs from primary study
8.2. Behaviour substitution	Prompt substitution of the unwanted behaviour with a wanted or neutral behaviour	*Alternatives for unsafe sex were presented . . .* *Carpenter* et al.[96]
8.4. Habit reversal	Prompt rehearsal and repetition of an alternative behaviour to replace an unwanted habitual behaviour	*Multiple use of 8.4* *Carpenter* et al.[96]
9.1. Credible source	Present verbal or visual communication from a credible source in favour of or against the behaviour	*The HIV positive gay narrator shared his personal experience with the audience, persuading them to protect themselves and their partners from HIV infection by having safer sex* *Hao* et al.[103]
9.2. Pros and cons	Advise the person to identify and compare reasons for wanting (pros) and not wanting to (cons) change the behaviour (includes 'decisional balance')	*. . . using decisional balance exercises to increase motivation for behaviour change* *Carpenter* et al.[96]
10.4. Social reward	Arrange verbal or non-verbal reward if and only if there has been effort and/or progress	*Counsellors listened for and reinforced statements of motivation consistent with safer sex strategies . . .* *Picciano* et al.[106]
11.2. Reduce negative emotions	Advise on ways of reducing negative emotions to facilitate performance of the behaviour	*. . . designed to decrease feelings of isolation and inferiority . . . negative feelings of associated with religious, societal, and familial rejection are also addressed* *Christensen* et al.[97]
13.2. Framing/ reframing	Suggest the deliberate adoption of a perspective or new perspective on behaviour (e.g. its purpose) in order to change cognitions or emotions about performing the behaviour (includes 'cognitive structuring')	*. . . including reframing self-justifications to clarify the reality of risk* *Coffin* et al.[98]
13.3. Incompatible beliefs	Draw attention to discrepancies between current or past behaviour and self-image, in order to create discomfort (includes 'cognitive dissonance')	*. . . designed to challenge viewers and prompt critical thinking by portraying (and providing vicarious experience of) dissonance, disequilibrium, and expectation failure* *Hirshfield* et al.[104]
13.4. Valued self-identify	Advise the person to write or complete rating scales about a cherished value or personal strength as a means of affirming the person's identity as part of a behaviour change strategy	*. . . the program focused on . . . a values sort card activity . . . (this is used to identify values that are important to the client and eventually use this knowledge to aid in their change process)* *Parsons* et al.[105]
15.2. Mental rehearsal of successful performance	Advise to practise imagining performing the behaviour successfully in relevant contexts	*. . . the counsellor asks the participant what he thinks will happen in the future. What does he think he will do in a similar situation? Mental rehearsal increases the likelihood that the client will put what he learned to use the next time he is in a potentially risky situation* *Dilley* et al.[100]
15.3. Focus on past success	Advise to think about or list previous successes in performing the behaviour, or parts of it	*. . . focused on reasons for protected or no anal intercourse, who initiated protection, feelings/thoughts around reduced sexual risk . . .* *Coffin* et al.[98]

Behaviour change techniques unique to interventions when removing behaviour change techniques shared with control groups

Table 5 shows the range of BCTs employed only in the intervention groups (i.e. disregarding BCTs also used in the corresponding control groups). It provides definitions of the BCT concerned and illustrative examples taken from the primary studies. *Table 6* illustrates the distribution of distinct BCTs present in interventions when removing BCTs used in both the intervention and control groups. It shows that a broad range of unique BCTs has been utilised within the interventions. Only 3 of the 16 groups of BCTs are not represented here; these are BCTs associated with 'scheduled consequences', those with a focus on 'covert learning' and those associated with 'antecedents'.

The most common groups of BCTs used relate to 'goals and planning' (across all selected studies, a BCT from this grouping is coded as present 12 times), 'identity' (BCTs from this grouping are represented nine times across all studies), 'social support' (appearing a total of seven times across all studies) and 'comparison of outcome' (again appearing a total of seven times across all studies).

In terms of the total numbers of individual BCTs used in interventions, removing those used also in control groups leaves a relatively small range of different BCTs. Christensen *et al.*[97] utilised the most unique BCTs in their intervention (11), while Parsons *et al.*[105] used nine, both Carpenter *et al.*[96] and Picciano *et al.*[106] used eight, Hao *et al.*[103] used six and Coffin *et al.*[98] used five, as did Dilley *et al.*[101] Hirshfield *et al.*[104] and Dilley *et al.*[100] used four BCTs and Eaton *et al.*[102] used three. The most commonly used unique BCTs were 'pros and cons',[96,97,102,103,105,106] 'goal-setting',[96,101,105,106] 'social support (emotional)',[96,103,105,106] 'framing and reframing'[98–101,105,106] and 'incompatible beliefs'.[100,101,103,104]

The use of theory within selected interventions

Table 7 shows that three studies were based on a single theory: Eaton *et al.*[102] and Dilley *et al.*[100,101] It shows that theories and models of behaviour were used to explain or predict behaviour in 9 out of 10 studies. A range of theories was reported. Christensen *et al.*,[97] Coffin *et al.*[98] and Hirshfield *et al.*[104] all reported using social cognitive theory.[198] Carpenter *et al.*[96] and Picciano *et al.*[106] use the information–motivation–behavioural skills model.[199] The theory of planned behaviour[200] is mentioned by Christensen *et al.*[97] and Hao *et al.*[103] The health belief model is also used by Hao *et al.*[103] Eaton *et al.*[102] utilised a conflict theory of decision-making.[201] In addition, Christensen *et al.*[97] utilised a theory of shame reduction, which posits shame as a major predictor of negative health behaviours.[202] Two further clusters of the use of theory are worthy of mention.

An additional cluster of studies[98,100,101] also used what is described as self-justification theory.[203] Although self-justification is not a formal theory, it is clearly used to explain or predict behaviour and merits some discussion here. Its basic premise rests on an imagined difference between 'online' thinking (e.g. heat of the moment) and 'offline' thinking (e.g. in the cold light of day). It introduces the importance of self-dialogue concerning the attribution of justifying unwanted behaviour. Through rehearsing these self-justifications in offline thinking, techniques and skills can be garnered that help people solve problems with their risk-related behaviour.

A further cluster of studies address stages of change theory: Carpenter *et al.*,[96] Coffin *et al.*[98] and Hao *et al.*[103] Carpenter *et al.*[96] used 'stages of change' as a motivational tool with all participants. Coffin *et al.*[98] do not specify how they used the theory. Hao *et al.*[103] also used 'stages of change' as a means of motivating and tailoring the intervention to the individual, although, again, in this study the theory was used to shape the intervention for all participants. In no study was 'stages of change' used to select participants for receipt of the intervention per se.

TABLE 6 Behaviour change techniques included within the primary studies

Author (year of publication)	BCTs								
	1. Goals and planning					2. Feedback and monitoring			
	1.1 Goal-setting (behaviour)	1.2 Problem-solving	1.3 Goal-setting (outcome)	1.4 Action planning	1.5 Review behaviour goal(s)	2.1 Monitoring of behaviour by others without feedback	2.2 Feedback on behaviour	2.3 Self-monitoring of behaviour	2.6 Biofeedback
Carpenter *et al.* (2010)[96]	p	p					p		
Christensen *et al.* (2013)[97]									
Coffin *et al.* (2014)[98]		p				p			p
Dilley *et al.* (2007)[100]	p	p	p	p					p
Dilley *et al.* (2002)[101]	p	p	p	p				p[a]	p
Eaton *et al.* (2011)[102]		p		p					
Hao *et al.* (2012)[103]				p					p
Hirshfield *et al.* (2012)[104]									
Parsons *et al.* (2014)[105]	p	p			p		p		
Picciano *et al.* (2007)[106]	p						p		
Total studies using each BCT	5	6	2	4	1	1	3	1	4

p, present BCT.
a Present BCT for diary intervention arm only.[99]
Shading used for BCTs that are present only in the intervention and not in the control.

3. Social support		4. Shaping knowledge		5. Natural consequences		6. Comparison of behaviour	
3.1 Social support (unspecified)	3.3 Social support (emotional)	4.1 Instruction on how to perform the behaviour	4.2 Information about antecedents	5.1 Information about health consequences	5.3 Information about social and environmental consequences	6.1 Demonstration of the behaviour	6.2 Social comparison
	p	p	p	p	p		
		p	p	p	p		
p							
p				p			
p				p			
p				p			p
p	p			p			
p				p		p	
p	p		p				
p	p			p			
8	4	2	3	8	2	1	1

TABLE 6 Behaviour change techniques included within the primary studies (*continued*)

	BCTs						
	7. Associations	8. Repetition and substitution			9. Comparison of outcomes		10. Reward and threat
Author (year of publication)	7.1 Prompts/cues	8.1 Behavioural practice/rehearsal	8.2 Behaviour substitution	8.4 Habit reversal	9.1 Credible source	9.2 Pros and cons	10.4 Social reward
Carpenter *et al.* (2010)[96]			p			p	
Christensen *et al.* (2013)[97]		p	p	p		p	
Coffin *et al.* (2014)[98]							
Dilley *et al.* (2007)[100]							
Dilley *et al.* (2002)[101]							
Eaton *et al.* (2011)[102]						p	
Hao *et al.* (2012)[103]	p				p	p	
Hirshfield *et al.* (2012)[104]							
Parsons *et al.* (2014)[105]						p	
Picciano *et al.* (2007)[106]			p			p	p
Total studies using each BCT	1	1	3	1	1	6	1

11. Regulation		12. Antecedents	13. Identity			15. Self-belief		
11.2 Reduce negative emotions	11x Increase positive emotions	12.5 Adding objects to the environment	13.2 Framing/ reframing	13.3 Incompatible beliefs	13.4 Valued self-identify	15.2 Mental rehearsal of successful performance	15.3 Focus on past success	Total BCTs per study (unique BCTs in brackets)
								10 (8)
p	p		p					11 (11)
			p				p	6 (5)
			p	p		p	p	11 (4)
			p	p		p	p	11 (12) (5)
								6 (3)
		p		p				10 (6)
				p				4 (4)
					P			9 (9)
	p							9 (7)
1	2	1	4	4	1	2	3	

TABLE 7 Use of theory in the development of interventions within included studies

Author (year of publication)	1. Theory/ model of behaviour mentioned	2. Targeted construct mentioned as predictor of behaviour	3. Intervention based on a single theory (rather than a combination of theories or theory and predictors)	4. Theory/ predictors used to select recipients	5. Theory/ predictors used to select/ develop BCTs	6. Theory/ predictors used to tailor BCTs to recipients	7. All BCTs are explicitly linked to at least one theory-relevant construct/ predictor
Carpenter *et al.* (2010)[96]	Yes	Yes	No	No	Yes	Yes	No
Christensen *et al.* (2013)[97]	Yes	Yes	No	No	Yes	No	No
Coffin *et al.* (2014)[98]	Yes	Yes	No	No	Yes	No	No
Dilley *et al.* (2011)[99]	Yes	Yes	Yes	No	Yes	No	No
Dilley *et al.* (2007)[100]	Yes	Yes	Yes	No	Yes	No	No
Dilley *et al.* (2002)[101]	Yes	Yes	Yes	No	Yes	No	No
Eaton *et al.* (2011)[102]	Yes	No	Yes	No	Yes	No	No
Hao *et al.* (2012)[103]	Yes	Yes	No	No	Yes	No	No
Hirshfield *et al.* (2012)[104]	Yes	No	No	No	Yes	No	No
Parsons *et al.* (2014)[105]	No	No	No	Yes	Yes	Yes	No
Picciano *et al.* (2007)[106]	Yes	No	No	Yes	Yes	No	No

8. At least one, but not all, BCTs are explicitly linked to at least one theory-relevant construct/ predictor	9. A group of BCTs are linked to a group of constructs/ predictors	10. All theory–relevant constructs/ predictors are explicitly linked to at least one BCT	11. At least one, but not all, theory–relevant constructs/ predictors are explicitly linked to at least one BCT	Overall theory score (range 0–8)	BCTs reported linked to theory-relevant constructs (range 0–2)	Constructs targeted by BCTs (range 0–2)
Yes	No	Yes	No	5	1	2
Yes	No	No	Yes	3	1	1
Yes	No	No	Yes	3	1	1
Yes	No	Yes	No	5	1	2
Yes	No	Yes	No	5	1	2
Yes	No	Yes	No	5	1	2
Yes	No	No	Yes	4	1	1
Yes	No	Yes	No	4	1	2
Yes	No	No	Yes	3	1	1
No	No	No	No	3	0	0
Yes	No	No	Yes	4	1	1

To what extent have studies used theories or predictors to select recipients for the intervention?

Two of the 10 studies reported using theories, or predictors, to select participants for the intervention.[105,106] However, it is not clear exactly how this was achieved. Parsons *et al.*[105] recruited men who were ambivalent about change (in that they were not already seeking treatment for sexual risk or their episodic substance use) in order to engage within a motivational-based intervention. They do not report the exact mechanism by which this was assessed. Similarly, Picciano *et al.*[106] employed tailored marketing strategies to attract men who were ambivalent about engaging in prevention services in order to then deliver a motivational-based intervention designed to enhance motivation and develop skills. Like Parsons *et al.*,[105] Picciano *et al.*[106] do not report if this was assessed in any formal way as part of recruitment.

Have studies utilised theory-congruent behaviour change techniques?

Table 7 shows the composite scores relating to three measures suggested by Prestwich *et al.*,[85] which reflect theory congruence. The measure of whether or not BCTs are linked to theory-relevant constructs shows that, overall, they were only partially linked. In contrast, the second measure assessing whether or not theory-relevant constructs shaped the choice of BCT shows that far more studies have theory-relevant constructs which are linked to BCTs. In terms of the items addressing the role of theory in developing the intervention, all of the interventions draw on theory to some extent.

Risk of bias

Table 8 provides details of the risk of bias. Despite three requests to all authors, only two authors provided protocols or intervention manuals.[99–101,104] These documents were utilised alongside the published papers to glean further information regarding bias.

In all other studies, information was garnered from published papers only. Generally, most studies were considered to be fair or good, with the study by Dilley *et al.*[99,100] being considered as fair, scoring low risk of bias on all items except 'other sources of bias'. Eaton *et al.*[102] and Picciano *et al.*[106] were the studies judged to be at least risk of bias, with the risk of bias on most of the domains being scored as either high or unclear.

TABLE 8 Risk-of-bias assessment for included studies

Author (year of publication)	Sequence generation	Adequate allocation concealment	Blinding of participants, personnel and outcome assessors	Incomplete outcome data addressed	Free of selective outcome reporting	Other sources of bias?
Carpenter *et al.* (2010)[96]	+	+	?	+	+	?
Christensen *et al.* (2013)[97]	+	+	–	?	+	–
Coffin *et al.* (2014)[98]	+	+	–	+	+	–
Dilley *et al.* (2011)[99]	+	+	+	+	+	?
Dilley *et al.* (2007)[100]	+	+	+	+	+	+
Dilley *et al.* (2002)[101]	+	+	?	–	+	+
Eaton *et al.* (2011)[102]	?	?	?	+	+	+
Hao *et al.* (2012)[103]		+	–	+	+	+
Hirshfield *et al.* (2012)[104]	+	+	–	+	+	–
Parsons *et al.* (2014)[105]	+	?	+	+	+	+
Picciano *et al.* (2007)[106]	?	?	––	?	+	?

+, 'yes', low risk of bias; –, 'no', high risk of bias; ?, unclear risk of bias.

Most studies demonstrated adequate sequence generation and allocation concealment. They were all relatively good at addressing incomplete data and reasonably free of selective outcome reporting.

The main domain on which studies either scored 'no' or 'unclear' was whether or not participants and/or personnel had been adequately blinded. Of particular note, within individual behaviour change interventions it is often obvious to participants that they have been assigned to the intervention arm rather than the control, particularly when the control is 'usual care' or a null comparison. Likewise, it is often not possible to blind those delivering or administering face-to-face interventions. Although such studies would score 'no' based on the given criteria, it could be argued that such lack of blinding is unavoidable and, hence, any bias is also unavoidable and should not be considered as impeding the quality of the study.

When studies scored 'no' or 'unclear' for 'other sources of bias', this was mainly because of baseline imbalance in the outcome measure or in factors related to the outcome measure, possibly a result of the small sample size and/or low participation rate reported.

Intervention fidelity

Table 9 shows the treatment fidelity. Summary scores of treatment fidelity ranged from 20%[102] to 68%;[105] therefore, no intervention had a high (> 80%) treatment fidelity rating overall. Studies that scored higher in design[96,100,103] gave detailed accounts content of interventions, and the number and length of contact for both treatment and control interventions. Dilley *et al.*[100] and Parsons *et al.*[105] both scored very highly for interventionist training, as they provided considerable detail on how providers were trained, how their skills acquisition was assessed, how training was monitored and what was expected of providers. This domain was not relevant for three studies,[96,97,104] as they were delivered online. Parsons *et al.*[105] was the only study that scored fairly highly for intervention delivery, providing details on how the methods ensured and assessed that the intervention was delivered as specified and adhered to by participants, that there were plans in place to assess the delivery of the active ingredients and proscribed components of the intervention and that there was a manual available. Most studies scored fairly poorly on intervention receipt (some scored 0%), which meant that they did not provide detail on how well participants understood the intervention, whether or not they had the skills to be able to comprehend the intervention or if the interventions took into account multicultural factors in relation to participants. None of the studies scored for intervention enactments, which detail how intervention skills are assessed beyond treatment.

Assessment of effectiveness

Overall, the trials included in this review reported positive findings and suggested that behavioural change interventions are effective in reducing risky sexual behaviour in HIV-negative MSM. However, these trials are heterogeneous, in terms of participant characteristics, the nature of the interventions evaluated, the length of follow-up and definition of risky sexual behaviour. Therefore, the estimated treatment effects in these studies varied substantially.

Risk-related behaviour outcomes

As noted in *Chapter 1*, HIV risk and attempts to measure it are complex and imperfect. However, all 10 trials measured behavioural outcomes related to HIV risk reduction (*Tables 10* and *11*). These include UAI,[96–106] number and type of sexual partners[102,106] and HIV disclosure.[104] UAI was the most commonly reported behavioural outcome relating to HIV risk; however, definitions of UAI differed among the studies, for example with respect to specificity of UAI (in general or specific to receptive or insertive UAI), partner type (casual or regular) or period of recall. Moreover, some studies also reported multiple measures of UAI.

TABLE 9 Intervention fidelity

Author (year of publication)	Study design		Interventionist training		Intervention delivery		Intervention receipt		Intervention enactment		Treatment fidelity	
	Score	% score	Score	% score	Score	% score	Score	% score	Score	% score	Total score	% total score
Carpenter *et al.* (2010)[96]	10/14	71	N/A (online)	N/A	2/7	29	1/5	20	0/2	0	13/28	46
Christensen *et al.* (2013)[97]	6/10	60	N/A (online)	N/A	3/7	43	3/5	60	0/2	0	12/24	50
Coffin *et al.* (2014)[98]	6/16	38	4/7	57	3/9	33	1/5	20	0/2	0	14/39	36
Dilley *et al.* (2007)[100]	12/17	71	6/7	86	2/8	25	0/5	0	0/2	0	20/39	51
Dilley *et al.* (2002)[101]	10/17	59	1/7	14	3/8	38	0/5	0	0/2	0	14/39	36
Eaton *et al.* (2011)[102]	6/17	35	1/7	14	0/9	0	1/5	20	0/2	0	8/40	20
Hao *et al.* (2012)[103]	13/17	76	1/7	14	5/9	56	0/3	0	0/2	0	19/38	50
Hirshfield *et al.* (2012)[104]	6/16	38	N/A (online)	N/A	1/8	13	0/5	0	0/2	0	7/31	23
Parsons *et al.* (2014)[105]	9/17	53	7/7	100	7/9	78	3/5	60	N/A	N/A	26/38	68
Picciano *et al.* (2007)[106]	11/17	65	5/7	71	5/8	63	0/5	0	0/2	0	21/39	54

N/A, not applicable.

TABLE 10 Risk of UAI (risk ratios)

Methodological aspects	Author (year of publication)								
	Coffin *et al.* (2014)[98]	[a]Dilley *et al.* (2002)[101]	[b]Dilley *et al.* (2011);[99] men of colour	[b]Dilley *et al.* (2011);[99] white men	Hao *et al.* (2012)[103]	[c]Hirshfield *et al.* (2012);[104] video	[c]Hirshfield *et al.* (2012);[104] web page	Parsons *et al.* (2014)[105]	Picciano *et al.* (2007)[106]
Follow-up	6 months	6 months	6 months		6 months	2 months		6 months	4 months
Effect estimate	Reported rate ratio (ratio of the intervention and control rates of change in mean value)	Estimated odds ratio based on data reported in the trial	Reported rate ratio		Reported relative risk (ratio of event rates in the two arms)	Reported odds ratio		Reported odds ratio (generalised estimating equation modelling)	Estimated odds ratio based on data reported in the trial
Definition	Receptive UAI events in the preceding 90 days	UAI with non-primary partners of unknown or discordant HIV status in the preceding 90 days	UAI with two most recent non-primary HIV non-seroconcordant male partners in the previous 90 days		UAI with any male sex partners in the previous 6 months	Any UAI with up to three most recent partners in the previous 60 days		UAI with casual partner in the last 30 days	UAI with unknown HIV status partner in the previous 90 days

a Intervention counselling and diary arm compared with the control arm.
b Dilley *et al.*[99] reported the findings separately for men of colour and white men.
c Trial with two intervention groups.

TABLE 11 Reduction in UAI (standardised mean differences)

Methodological aspects	Author (year of publication)				
	Carpenter *et al.* (2010)[96]	[a]Dilley *et al.* (2011);[99] men of colour	[a]Dilley *et al.* (2011);[99] white men	Eaton *et al.* (2011)[102]	Picciano *et al.* (2007)[106]
Follow-up	3 months	6 months		3 months	10 months[b]
Definition	Number of UAI acts with partners of HIV-positive/ HIV-unknown status in the previous 90 days	Number of episodes of UAI with two most recent non-primary HIV non-seroconcordant male partners in the previous 90 days		Number of UA sex acts with HIV-positive/ HIV-unknown partners in the preceding month	Number of episodes of URAI with non-primary partner in the previous 90 days

UA, unprotected anal; URAI, unprotected receptive anal intercourse.
a Dilley *et al.*[99] reported the findings separately for men of colour and white men.
b No 4-month data were available.
Note
All effect estimates were estimated based on data reported in the trials, expressed as standardised mean differences.

In an attempt to draw comparisons across the studies, we had to provide some consistent way of looking across these varied measures of HIV risk. We decided to present the findings of the most risky type of UAI reported within individual studies. This was based on contemporary knowledge of HIV transmission that shows that receptive unprotected intercourse with casual partners of HIV-unknown or HIV-positive status carries more risk than insertive unprotected sex. Similarly, unprotected sex with a regular partner (in which case status disclosure is more likely to occur) carries less risk than that with a casual partner, and unprotected sex with another HIV-negative man carries no risk of HIV transmission at all. Although we acknowledge that unprotected sex with a HIV-positive person with an undetectable viral load carries very little risk of transmission, no studies reported here examined the viral load of positive partners of the participants.

We were able to express the reduction of UAI risk as risk ratios based on data from seven trials[98–101,103–106] and as standardised mean difference in four trials.[96,99,100,102,106] Two trials reported outcomes as both rates and means.[100,106] One trial did not report quantitative findings regarding change in UAI, even though it was one of the outcome measures evaluated.[97] The majority of trials reported outcomes at 6 months; when data were available, we presented outcomes at this time point. For trials without a 6-month follow-up, we presented data at the follow-up period closest to 6 months.

With the exception of the trial by Hirshfield *et al.*,[104] who found no difference in sexual behaviour between the intervention and comparator arms at 4 months, all other trials reported a reduction in UAI (see *Table 10*). In particular, three trials reported a statistically significant reduction in UAI risk in the intervention arm.[99,100,103,105] All trials, with the exception of that by Picciano *et al.*,[106] reported a reduction in mean UAI episodes in the intervention arm (see *Table 11*).

Other reported key outcomes

In general, the trials reported that 'other' outcomes were better in the intervention arm than in the control arm (*Table 12*). However, these are not primary outcomes and the trials were typically underpowered for the detection of statistically significant differences. Trials that evaluated outcomes at multiple time points suggest the possibility of greater risk reduction over time. However, even in the longest trial participants were followed up for only 12 months. In addition to behavioural outcomes, one trial also reported cognitive outcomes,[102] expressed as condom use self-efficacy and HIV risk perceptions.

TABLE 12 Other outcomes reported

Author (year of publication)	Other relevant outcomes reported	Summary of reported results
Coffin *et al.* (2014)[98]	Number of UAI events	Risk ratio 1.03 (95% CI 0.58 to 1.83)
	Number of UAI partners	Risk ratio 1.06 (95% CI 0.68 to 1.65)
	Number of UAI events with three most recent non-primary partners	Risk ratio 0.75 (95% CI 0.51 to 1.12)
	Number of serodiscordant UAI events	Risk ratio 0.61 (95% CI 0.34 to 1.08)
	Number of insertive UAI events	Risk ratio 1.34 (95% CI 0.69 to 2.58)
	Number of condom-protected anal intercourse events	Risk ratio 1.29 (95% CI 0.43 to 3.86)
Dilley *et al.* (2002)[101]	Proportion of participants who reported UAI at 12 months (intervention counselling and diary compared with control)	33% vs. 44%
	Mean change in episodes of UAI, baseline to 12 months (intervention counselling and diary compared with control)	–2.90 vs. –0.15
Hao *et al.* (2012)[103]	UAI with regular male sex partners at 6 months	Relative risk 0.8 (95% CI 0.6 to 1.0)
	UAI with casual male sex partners at 6 months	Relative risk 0.7 (95% CI 0.5 to 1.1)
	HIV incidence rate at 6 months	Hazard ratio 0.83 ($p > 0.05$)
	Syphilis incidence rate at 6 months	Hazard ratio 0.82 ($p > 0.05$)
Hirshfield *et al.* (2012)[104]	HIV disclosure (full disclosure) at 60 days	Odds ratios: video, 1.32 (95% CI 1.01 to 1.74); web page, 1.11 (95% CI 0.81 to 1.51)
	HIV infection testing at 60 days	Odds ratios: video, 1.08 (95% CI 0.75 to 1.55); web page, 0.97 (95% CI 0.61 to 1.54)
Parsons *et al.* (2014)[105]	Day-level odds of UAI at 3 months	Odds ratio 0.78 (95% CI 0.67 to 0.91)
	Day-level odds of UAI at 9 months	Odds ratio 0.42 (95% CI 0.35 to 0.51)
	Day-level odds of UAI at 12 months	Odds ratio 0.43 (95% CI 0.35 to 0.52)
Picciano *et al.* (2007)[106]	UAI: receptive with non-primary partners	Adjusted relative risk 1.01 (95% CI 0.69 to 1.48)
	UAI: insertive with non-primary partners	Adjusted relative risk 0.88 (95% CI 0.64 to 1.21)
	UAI: receptive with primary partners	Adjusted relative risk 1.82 (95% CI 1.15 to 2.90)
	UAI: insertive with primary partners	Adjusted relative risk 1.35 (95% CI 0.86 to 2.14)
Carpenter *et al.* (2010)[96]	UIAI, URAI, UIOI, UROI	Univariate analysis showed reduction for all outcomes
Dilley *et al.* (2007/2011)[99,100]	Mean number of UAI at 12 months (men of colour)	1.8 (SD 2.4) vs. 2.1 (SD 3.8)
	Mean number of UAI at 12 months (white men)	1.9 (SD 3.4) vs. 2.2 (SD 6.0)
Eaton *et al.* (2011)[102]	Mean condom use self-efficacy at 3 months	5.62 (intervention arm) vs. 5.25 (control arm)
	Mean risk perception	9.18 (intervention arm) vs. 8.89 (control arm)
	Mean number of HIV-positive or HIV-unknown status partners	0.49 (intervention arm) vs. 1.47 (control arm)

SD, standard deviation; UIAI, unprotected insertive anal intercourse; UIOI, unprotected insertive oral intercourse; URAI, unprotected receptive anal intercourse; UROI, unprotected receptive oral intercourse.

Exploratory meta-analysis

As an exploratory analysis, we pooled the UAI risk ratios from the trials (see *Tables 10* and *11*). Overall, there is a statistically significant reduction in the risk of UAI (risk ratio 0.75, 95% CI 0.62 to 0.91). However, there is much clinical and methodological and statistical heterogeneity ($I^2 = 57\%$, $\tau^2 = 0.04$) among these studies, and this pooled estimate must be interpreted with caution. Additional exploratory a priori subgroup analyses were also carried out. Based on the mode of delivery of the interventions, the results suggested that face-to-face delivery may be more effective than interventions delivered via the telephone or online (*Figure 2*). Based on the proximity to HIV infection testing and implementing the interventions, the results suggest that immediately after testing may be associated with greater treatment effects (*Figure 3*).

In order to explore the relationship between behavioural change components and potential summary effect size, further subgroup analyses were also carried out. To illuminate the differential role of BCTs within interventions, interventions were divided in two: those interventions dominated by BCTs from the 'goals and planning' and 'identity' groups and those whose BCTs were more heterogeneous. Interventions containing 'goals and planning' and 'identity' BCT components were potentially more effective than those with heterogeneous BCT components (*Figure 4*). Similarly, in terms of the measure of theory-congruent BCTs, a score of ≥ 4 was potentially more effective than those with score of < 4 (*Figure 5*). There was no apparent trend in relation to number of BCTs.

We also explored the feasibility of undertaking indirect comparisons across the interventions by anchoring on the 'control' group. However, on reviewing the evidence, it was clear that control groups are heterogeneous across the studies, and cannot be considered as a common connecting treatment. Furthermore, it was clear that such an analysis with the existing data would violate the fundamental assumptions on consistency and transitivity. We therefore followed the criteria set out in *Chapter 2*, which concluded that going beyond the stratified pairwise meta-analysis would not add value to our understanding of the existing evidence.

It may be less advantageous to utilise interventions that are poorly targeted, delivered only via digital and other electronic media, and adopt a range of theoretical perspectives. For example, Hirshfield *et al.*[104] and Picciano *et al.*[106] were the only researchers to include HIV-positive and HIV-negative men (see *Table 9*). They employed media-based interventions that were not delivered face to face (*Figure 6*), not delivered immediately after testing (*Figure 7*) and based on a relatively heterogeneous range of behaviour change theories (see *Figures 4* and *5*). They also reported relatively low effect sizes. This indicates that there may be important attributes of intervention, which potentiate impact on risk-related behaviour. This is explored in greater depth in the next chapter.

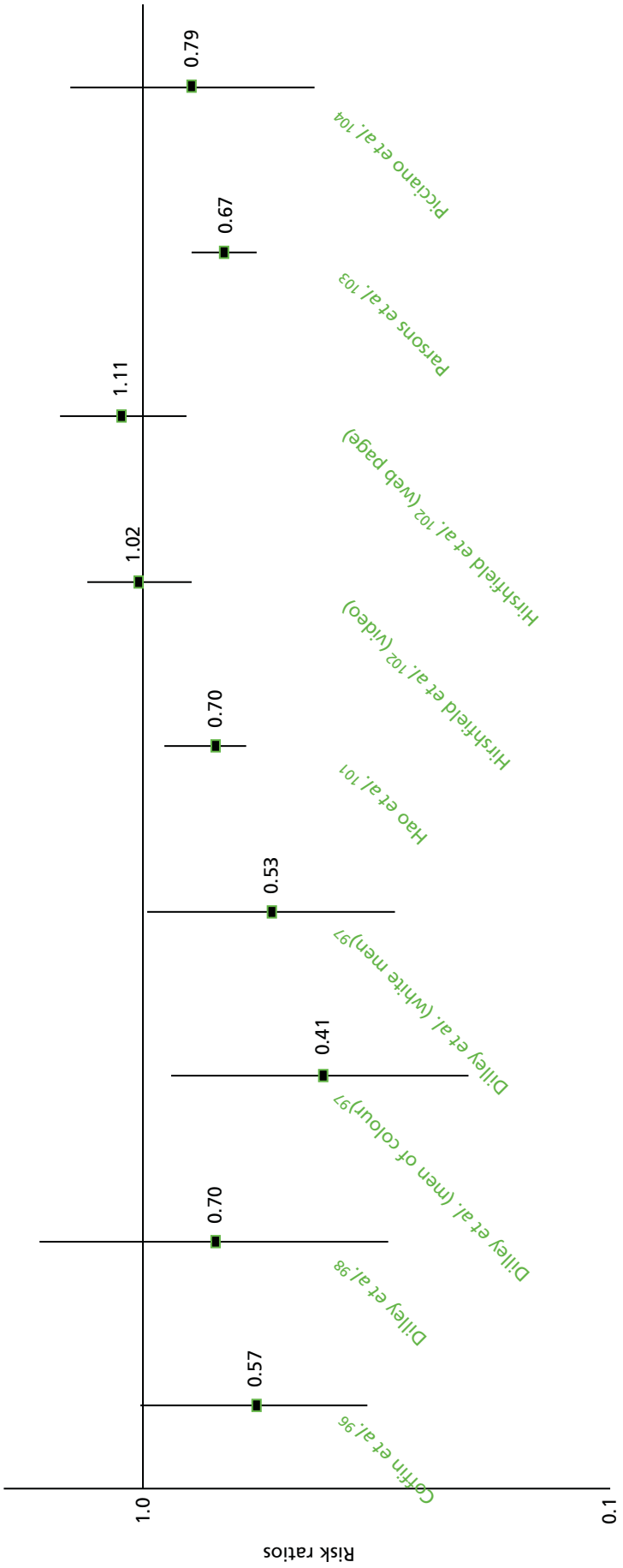

FIGURE 2 The distribution of risk ratios.

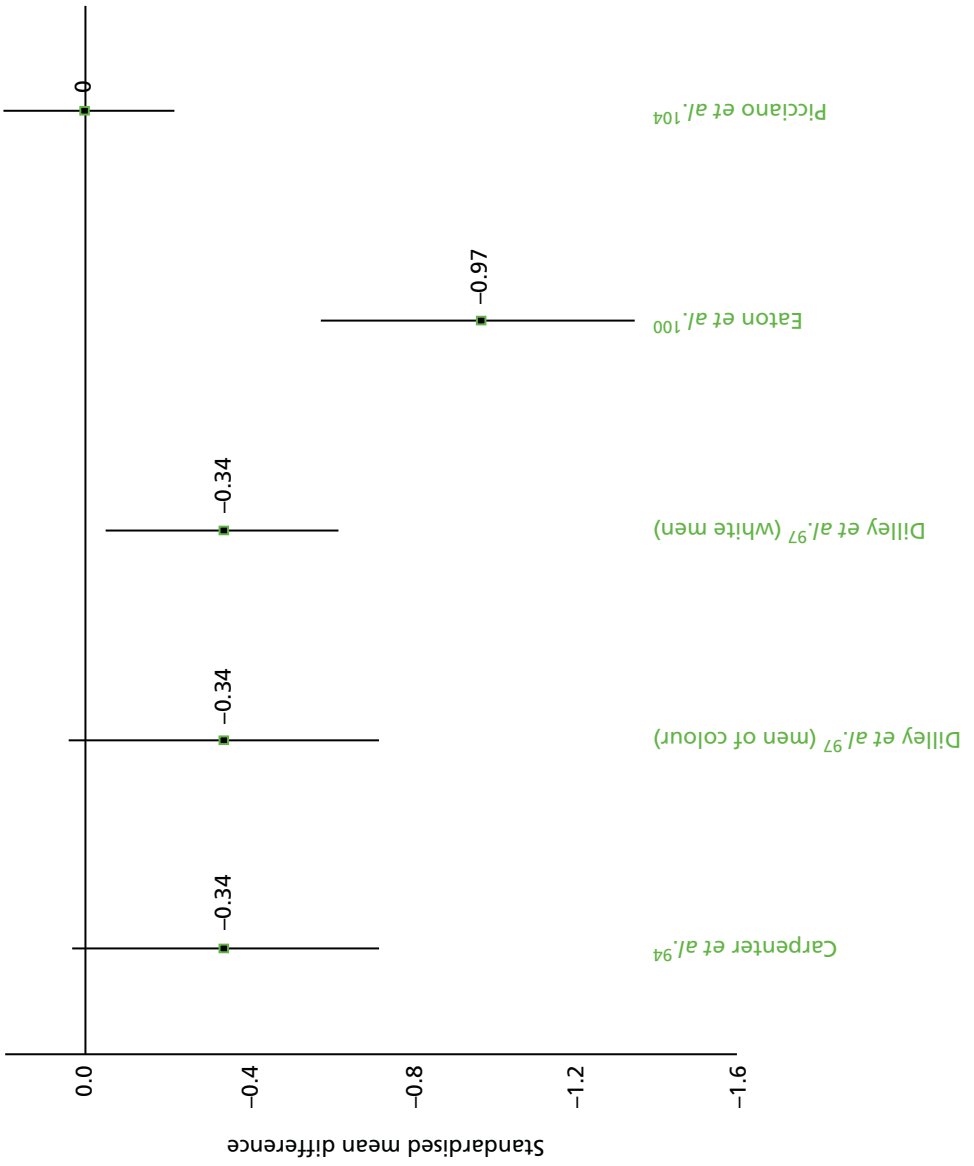

FIGURE 3 The distribution of standardised mean difference.

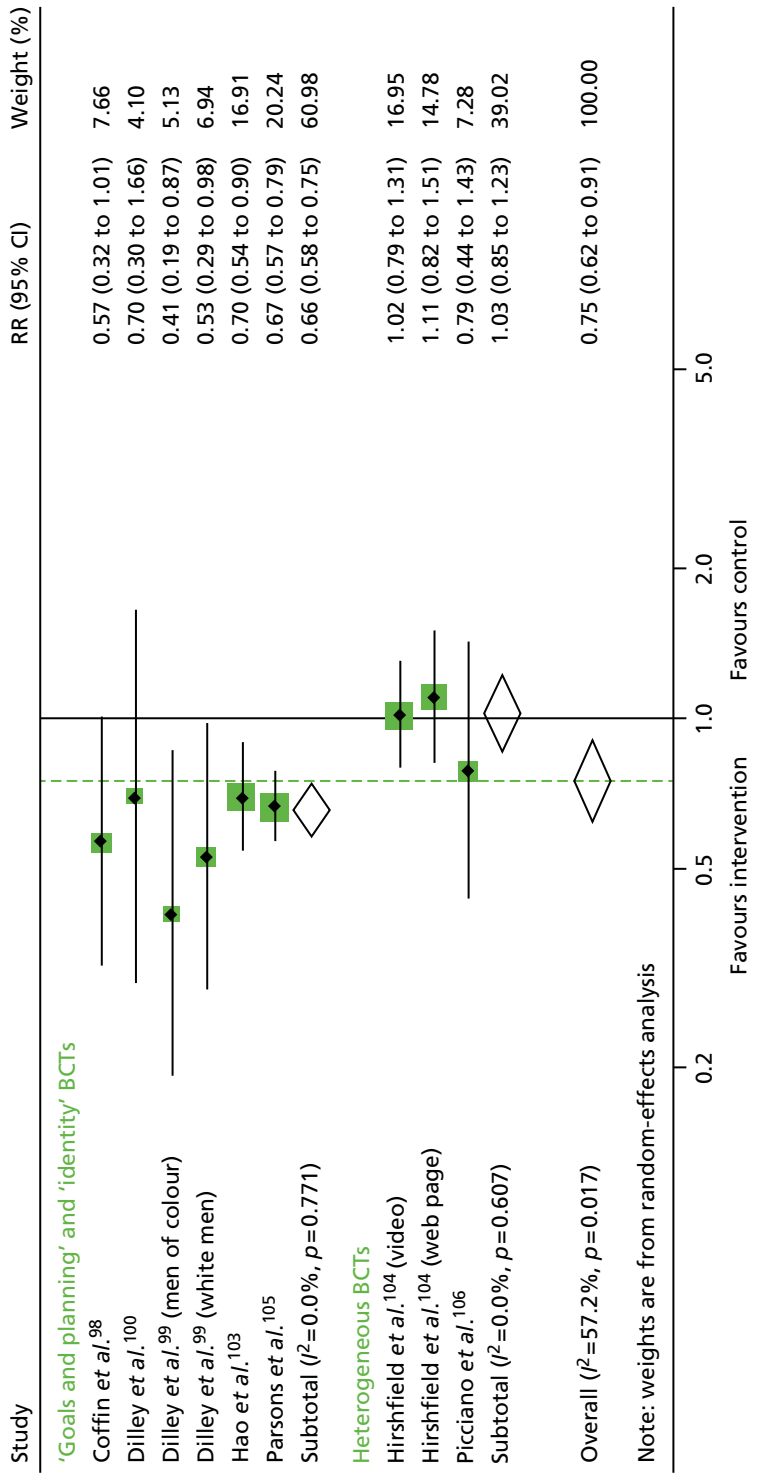

FIGURE 4 Risk ratios of UAI stratified by BCTs. RR, relative risk/risk ratio.

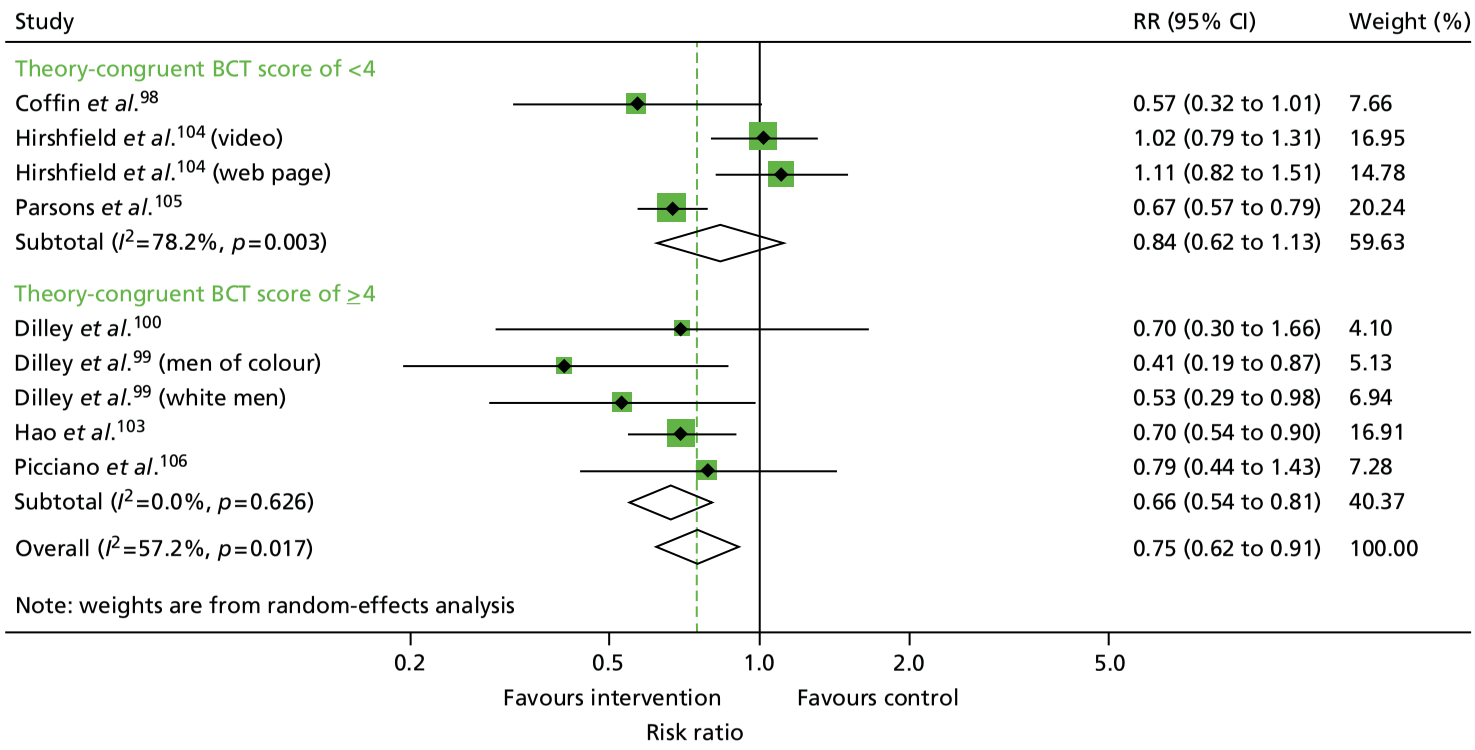

FIGURE 5 Risk ratios of UAI stratified by theory-congruent BCT scores. RR, relative risk/risk ratio.

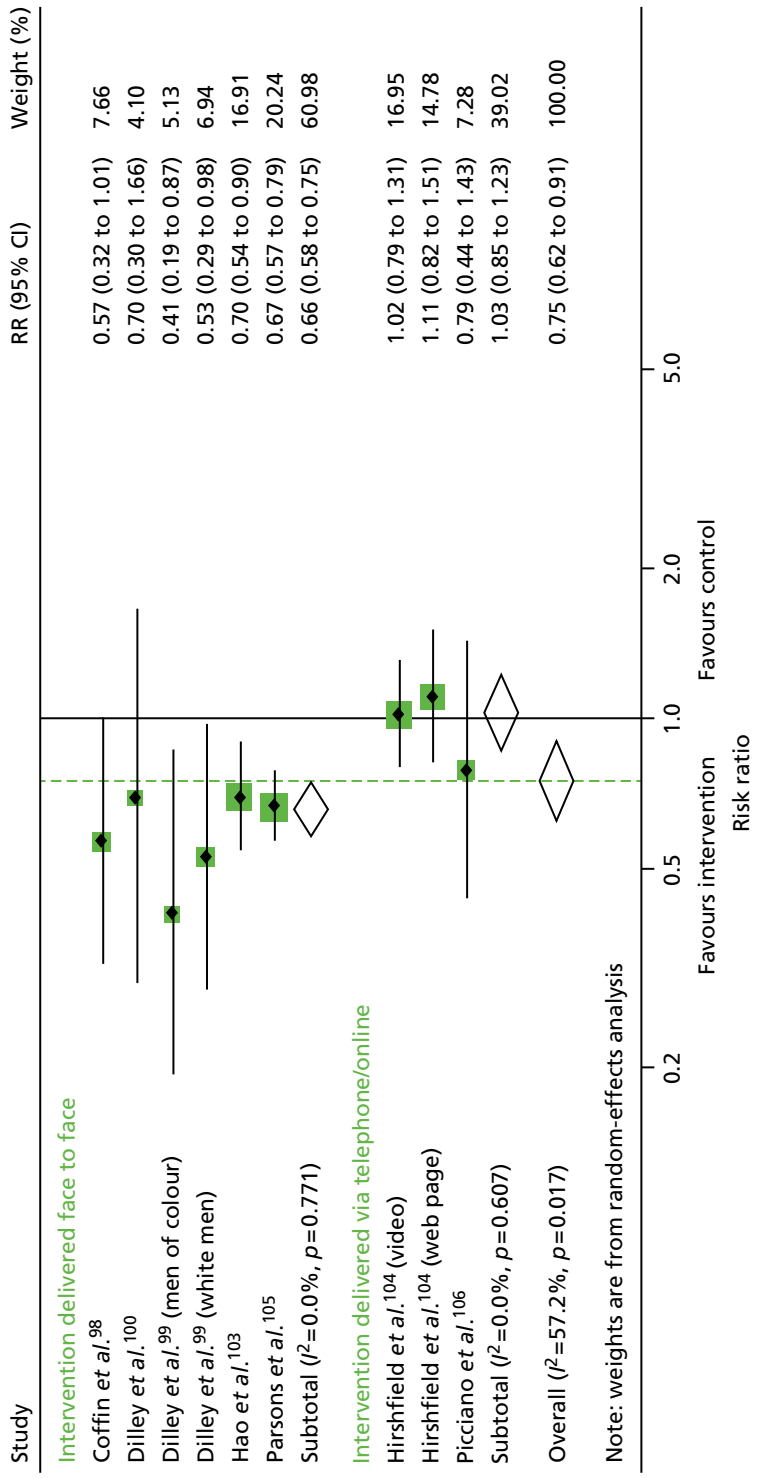

FIGURE 6 Risk ratios of UAI stratified by mode of delivery. RR, relative risk/risk ratio.

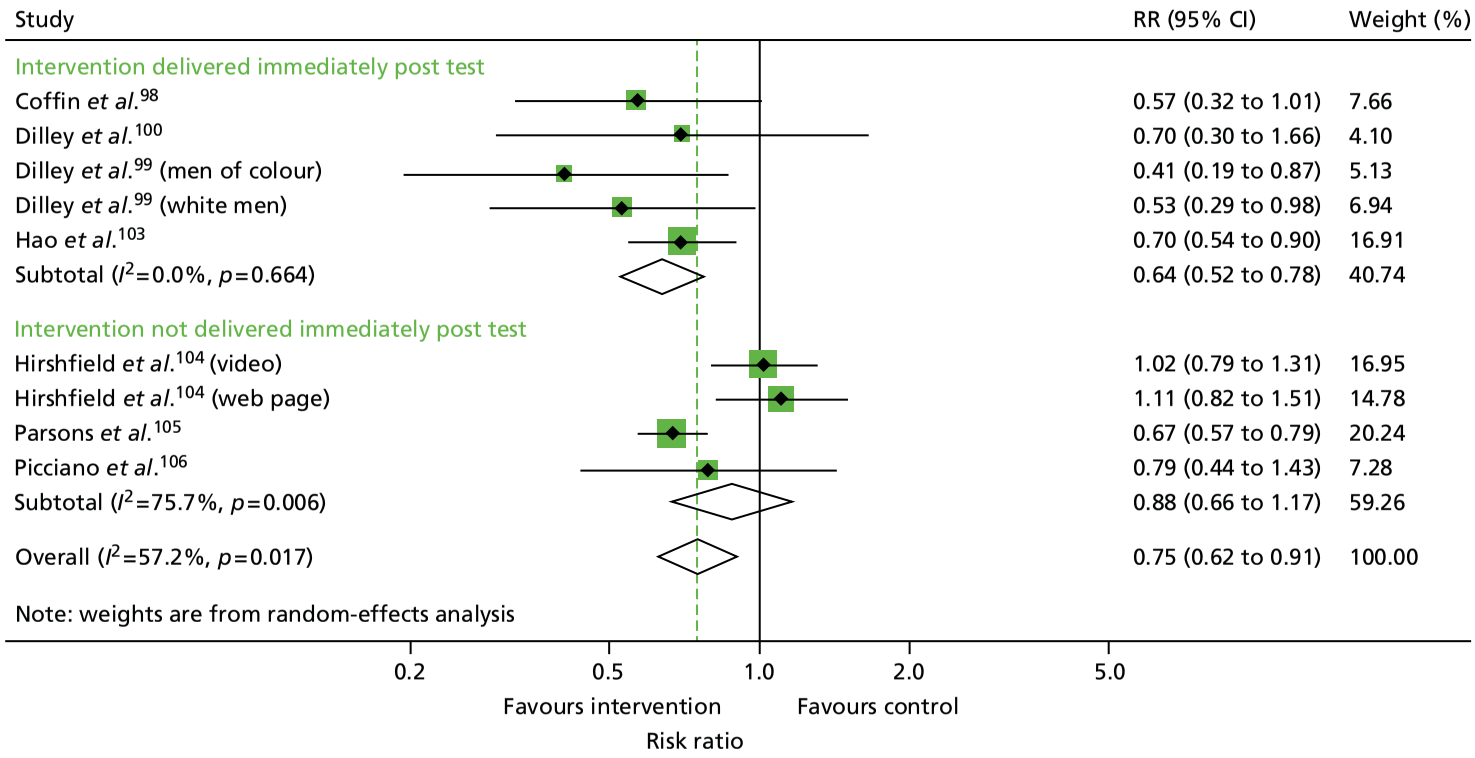

FIGURE 7 Risk ratios of UAI stratified by proximity to testing. RR, relative risk/risk ratio.

Chapter 4 Realist synthesis of interventions

Introduction

The previous chapter highlighted how exploratory meta-analyses suggested that brief behavioural individual-level interventions benefit MSM in terms of reducing HIV risk-related behaviour. However, the intervention effect is difficult to interpret because of the range of uncertainties outlined earlier (e.g. the limited number of studies included within the review, variations in outcome measures, recall periods and other aspects of study design such as discrepancies in sample size/power, the nature of the comparator condition, the proximity of interventions to the HIV infection testing process and heterogeneity in terms of mode of delivery).

An original objective of the funded research was to organise and host an expert event to enable (1) the synthesis and (2) the translation of the review findings to develop a candidate intervention ready for manualisation. Given the limitations of the meta-analytic perspectives possible in the study and the resulting complexity of synthesising study findings, alternative approaches to identifying a candidate intervention suitable for manualisation have been adopted.

A range of qualitative approaches are available to synthesise complex and heterogeneous evidence. For example, approaches such as metasynthesis, metaethnography, metanarrative and other forms of thematic analysis are often used in health research. These approaches to qualitative synthesis often aim to identify patterns of findings across a range of studies (metasynthesis, metaethnography and narrative synthesis in particular) rather than seeking to identify a particular the causal mechanism that underpins given interventions. Realist synthesis is particularly useful when data are both quantitative and qualitative. Finally, realist synthesis adopts a particular theory-driven approach to the identification of mechanisms in individual interventions and studies, and then seeks to focus on recurrent relationships between concepts (known as demiregularities) rather than focusing its synthesis on individual concepts, as many other approaches do.[204]

'Theory' here does not relate to the formal theoretical frameworks or models used within some disciplines to empirically explain variance in outcome measures. Instead, theory in this approach is understood as a heuristic and explanatory device, whereas the articulation of theory in this approach may reflect existing theoretical assumptions and frameworks, or it may not. For this reason, the approach adopted here reflects the explanatory-based content of primary studies and builds theory (sometimes called a 'programme theory') that facilitates the establishment of possible causations and inferences about why certain outcomes are generated in particular contexts.[205–207] In this way, 'realist synthesis' is a theory-driven methodology to evaluate complex interventions, ascertaining what works, for whom, and in what contexts.[208]

Unlike conventional reviews, realist synthesis is explanatory rather than summative. Our meta-analyses have highlighted that individual-level behaviour change interventions among MSM are highly heterogeneous, presenting major challenges in drawing conclusions about how they work. Realist synthesis identifies and articulates 'programme theories' (which detail why and how an intervention works) through focusing mainly on the context and mechanisms in which complex interventions work or do not work. In a realist synthesis data are used to iteratively improve programme theories and build a refined framework capable of shaping future interventions. Within a selected domain, it provides an opportunity to gain novel perspectives not occluded by disciplinary assumptions and dogma.

We conducted a post hoc realist synthesis of the 11 included papers, with the aim of confirming, or refuting, key aspects of interventions related to reducing HIV risk-related behaviour. This required equal attention to the papers that reported a successful intervention and those that reported that the

intervention added little to the effects of a control arm; therefore, articulating fully the mechanisms within the intervention components to understand how they worked or did not work.

Realist synthesis begins with an exploration of existing theories or models in order to provide an initial framework as a reference point for data extraction and interpretation. This initial framework can then be consulted, refined and tested using data from the review, iteratively refining key ideas suitable for future intervention development.

In order to develop the initial framework, several health behaviour change models and theories were integrated. The expertise and knowledge of members of the research team was combined with the key assumptions reflected in the formal theories utilised within the review, including the information–motivation–behavioural skill model,[199] social learning theory,[198] the theory of planned behaviour[200] and the health belief model.[209] In this way an initial framework was developed which provided a comprehensive scheme of understanding how interventions work and why. Given the individual-level nature of interventions included within the review and the hypothesised mechanism of action implicit within their underlying approaches, such a framework is psychological and primarily concerned with the individual and their mental world. In other words, it is concerned with illustrating behaviour change within the individual and in relation to their thoughts and feelings.

Our initial framework (*Figure 8*) illustrates the assumed personal resources and characteristics that clients bring to the intervention. Given that the interventions included within the review were motivational in nature, clients were also assumed to have, or to develop, intentions to change behaviour. In many psychological models, intentions together with attitudes and beliefs are expected to predict whether or not the intervention 'works'. Features of the intervention are assumed to activate, promote or support necessary changes in behaviour that lead to desired outcomes. Individuals' belief in their own capacity to enact change is also widely assumed to be an important aspect of behaviour change and is reflected in a range of concepts, such as perceived behavioural control, health locus of control or, most commonly, self-efficacy. As a result, within the initial framework, self-efficacy was specified as a possible moderator; specifically, its presence may increase the influence of the intervention in delivering behaviour change.

Analytical methods and synthesis

Realist synthesis involves the extraction of contexts, mechanisms and outcomes, and the interpretation of the relationships between them. These entities are inferred from studies through a sustained period of examination.

Contextual factors affect whether or not the intervention works, and can include environmental factors, intervention design or personal characteristics. Mechanisms are usually hidden processes that explain why the intervention works. Contexts activate mechanisms. Outcomes include both intended and unintended results. We fully acknowledge that several of these factors are likely to be episodic or infrequent in the MSM population, and interventions and, in particular, mechanisms that required a large degree of interpretation and abstraction to identify were discussed with another reviewer (PF), who approached emerging patterns in the data and the resultant theory with social science expertise and extensive knowledge of sexual health interventions. The primary reviewer (HH) was experienced in realist review methodology and in research about health-care interventions. Her background was in improvement science, with little experience of either health psychology or the domain of sexual health. This offered an advantage in that the process of data extraction, interpretation and abstraction was free from a priori psychological theoretical, conceptual or disciplinary assumptions. This allowed us to identify where the model developed in line with existing theory and where it departed from our advanced conventional understanding about sexual health behaviour change.

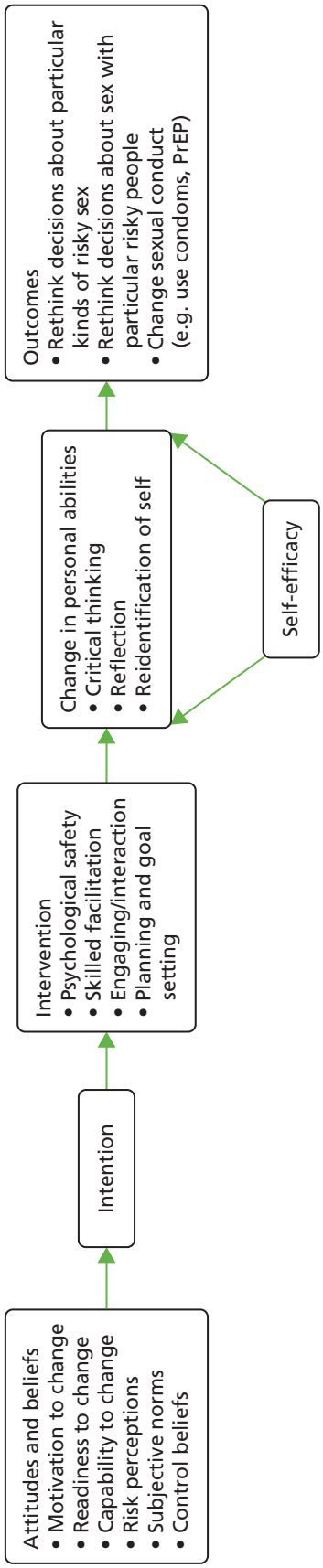

FIGURE 8 Initial framework.

Realist synthesis involves several iterative stages: familiarisation, individual context, mechanism and outcome (C-M-O) configurations, patterns across C-M-O configurations, the development of general statements and the development of explanatory theories that can then be used to formulate hypotheses in a final refined framework.

Following the construction of an initial framework, a familiarisation phase commenced, to enable the primary reviewer to understand the patterns of intervention characteristics (sample, setting, theory-based components, interventions and BCTs) and outcomes. The reviewer read and re-read the papers, in consultation with summary data from the meta-analysis, to extract possible contexts (which included any important features of the intervention itself), mechanisms and outcomes (which may themselves be interlinked). Extracted information included study setting and population, participant demographics and baseline characteristics, descriptions of the intervention and control conditions, study methodology, intervention completion rates, outcomes and suggestions by the authors about possible mechanisms of action of the chosen intervention strategies. Such information was extracted from the introductions, methodology and descriptions of the interventions (and in cases when the intervention did not demonstrate effectiveness, extractions were also taken from the control/usual care arm) and from the results and discussion sections of each paper.

All potentially important information that the reviewer considered to be contributory to the refinement of our initial framework was categorised as being initially a context, mechanism or outcome. These categories were then used to draft C-M-O configurations for each paper, describing how each contextual factor interacted with mechanisms to produce outcomes (those measured by the original authors, as well as unintended outcomes that were specified in our initial framework). This took the form of diagrams with interlinking arrows between each C-M-O, along with explanatory notes to justify its categorisation. Between 4 and 15 individual, whole or partial C-M-Os were extracted from each paper, although many of the papers contained similar configurations. *Appendix 4* summarises the C-M-Os across all papers. However, it should be noted that this table depicts only summary data to the end point of this process; it does not, and cannot, capture the iterative process of exploring the relationships between C-M-O variables, which sometimes involves adjustments to their categorisation (e.g. mechanisms can became contexts, or contexts can became mechanisms).

Then, C-M-O configurations were explored for patterns, across the interventions detailed within the studies, and by constant comparing and contrasting variables between studies, seeking confirmatory and contradictory findings. This allowed comparison of which mechanisms were activated across different contexts. In this way, explanatory theories concerning statements about what works, for whom and in what circumstances were formulated. This process was conducted in tandem with continual revisitation of the initial framework, which was devised to guide analysis and interpretation for the synthesis (see *Figure 8*).

General statements or hypotheses were derived from utilising processes of abstraction, with special attention paid to areas of confirmation or divergence from the initial framework. The aim of the synthesis was to refine the initial framework explaining how the interventions detailed within the review worked, with a specific focus on the mechanisms and features of the interventions, either explicit or implicit, which may have had casual effects. Throughout the process of realist synthesis there was a gradual developmental focus from the specific to the general (in other words, analysis and interpretation changed in scope from specific statements about specific interventions in specific papers, to more global statements about how individual behavioural interventions work more broadly). Theming and organisation of these statements, using the initial framework as a guide, resulted in three explanatory theories, which articulated the underlying processes by which interventions are expected to operate.

A distilled collection of features and associations was identified. This is presented in *Table 13*.

TABLE 13 Summary of key C-M-Os (unconfigured)

Contexts	Mechanisms	Outcomes
Storytelling/narration/explication	Shame	Self-regulation
Third-party neutralisation of confrontation with evidence	Educationally sensitive moment	Behavioural outcomes
Quantification of risk with feedback from pre-assessments	Recall and associated discomfort	Increased awareness
Ownership and responsibility	Identification of (lack of) control	Self-efficacy
Training and supervision of staff	Goal-setting	Confidence
Identification of self-justifications and assumptions about risk	Mobilising individuals own change resources	
Subject norms/perceptions of 'wrong'	Tailored intervention	
	Reframing	
	Critical thinking	
	Self-worth and motivation	
	Openness/reversal of internalisation	
	Opportunity to practice skills	

Explanatory theories

The theming and organisation of statements generated the formation of three key explanatory theories (which capture and articulate the underlying and general logic about the processes that create outcomes).[210] These each provide explanations about how individual HIV risk-related behaviour change interventions work. Each contributes directly to the refinement of the final explanatory framework (*Figure 9*).

The only assumptions that structure the realist review were that interventions should be face to face and one to one after testing, based in some kind of counselling format, targeted at reducing the risks for high-risk clients, and not aiming to achieve 'reach' (i.e. increase engagement in testing or counselling).

Theory 1: explication of behaviour

Interventions that include both the quantification and the detailed recall and narration of sex events and associated risk achieve several important mechanistic outcomes. This tends to be accomplished through the pre-assessment and measurement of existing risk. First, these explicit and specific disclosures increase the personalised focus of the intervention and, therefore, its applicability and perceived personal relevance to the client.

Second, measurement and story-telling confront clients with their own behaviours. The intervention provides a context in which the client experiences his conduct with some degree of objectivity. Dilley *et al.*[101] also utilised diaries with similar intentions that clients 'own' their behaviours. These mechanisms induce the feelings necessary to mobilise clients' own change resources; they also utilise uncomfortable emotions in the process of recall, including, in some circumstances, a moderate level of shame. Here, it is important that interventionists differentiate between shame associated with risky practices or behaviours and shame that may potentially be associated with gay identity. By providing an opportunity for key events to surface through narration, intervention contexts become primed for future recall, which may in turn interfere with habitual or ingrained thought patterns, feelings and self-justifications.

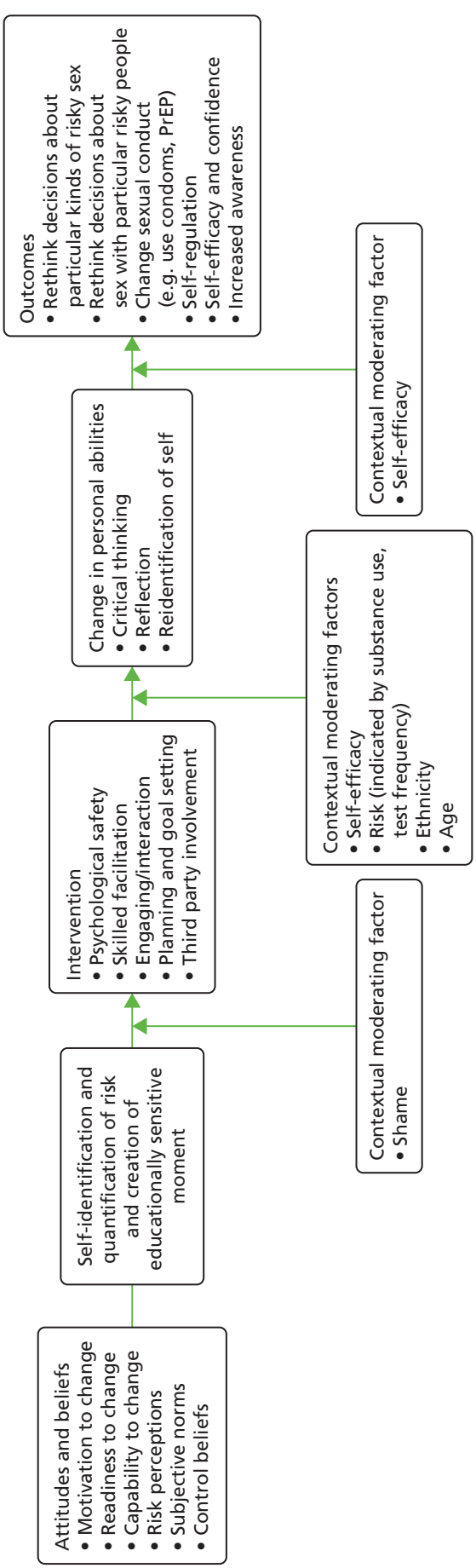

FIGURE 9 Refined framework.

When these intervention components are in place within the context of interventions, they create an educationally sensitive moment, during which the client is suitably exposed to new realities about his risk-related behaviour and has some affective vulnerability and, therefore, his readiness to change and his motivation may increase.

Theory 2: exploration through facilitated reappraisal and discussion

Within the context of the intervention following the identification and confrontation of risk-related behaviour, highly skilled facilitation is necessary to capitalise on increased motivation to change behaviour, to safely reappraise potentially damaging thoughts and feelings (e.g. feelings of shame and breaches of perceived subjunctive norm associated with the risk-related behaviour), to critically reframe beliefs and expected future risk-related behaviour, and to promote positive messages regarding the client's skills and abilities with regard to future behaviour. This theory aims to highlight the importance of providing a context within which to create suitable supporting conditions to explicate and explore facts concerning risk-related behaviour, but not so much that the exposure discourages engagement and openness.

Highly skilled facilitated discussion provides clients with focused attention and, in turn, increases self-worth and motivation. Moreover, it creates a psychologically safe environment to explore and redefine behaviours, sometimes through calibration with other similar individuals' profiles and their accounts of their risk-related behaviour. The generation of trust between a client and an interventionist encourages openness, a process important in reversing any internalisation of negative thoughts and feelings associated with prior behaviour.

However, Dilley *et al.*[101] identified that, when counselling sessions were repeated, risk-related behaviour increased. Repeated counselling may lead to the normalisation of risk-related behaviours, and increases in their subsequent acceptability. It is efficacious, for our identified target client base, that one-to-one individual-level behaviour change interventions are one-off.

Theory 3: enabling control through third party

Studies that included some form of third-party/person involvement or representation (i.e. not the client or the counsellor), through video, graphic novels or simulation, seemed to generate mechanisms related to the neutralisation of an otherwise intense didactic counsellor–client interaction. Third parties also contributed to the client's differentiation of risk in relation to those that are controllable and those that are less controllable. Furthermore, third parties enabled the increase of perceived control around the former. When the client has identified what it is possible to change, target behaviours are more easily identified and, in some cases, practised. For example, in the gaming intervention described by Christensen *et al.*,[97] newly self-constructed sexual skills were practised in simulations and effected through immersion in highly charged and culturally relevant experiences. The completion of a sequence of open-ended behavioural rehearsals provided clients with an opportunity to exert control or autonomy when they may have previously struggled in 'real life'.

Another important aspect of this theory is the similarity between characters and target audience, achieved via careful selection of characters in visual aids including graphic novels and simulation games. A variant on this is to afford the client control over the selection of his 'avatars', which may act to increase efficacy of the intervention's messages through increased feeling of association and self-hood.

Finally, this theory postulates that increasing perceived control over behaviour will foster realistic goal-setting and planning, which will in turn nurture new self-regulating behaviours and a sense of responsibility.

Revisions to the framework and take home messages

Although the refined framework (see *Figure 9*) and explanatory theories are intended to be general and applicable to many populations, some aspects of some interventions appear to be potentially sensitive to psychosocial and sociocultural dimensions. For example, the personalisation of interventions of interventions may be amplified when there is a resonance between client and particular elements of the

intervention. Individuals who demonstrate increased risk-related behaviours may benefit most from risk-reducing interventions; interventions that can accommodate a focus on substance use will facilitate the disclosure of substance use within the intervention, for example. Similarly, the ways interventions are delivered may be important; for example, gaming formats may have greatest efficacy with groups who commonly engage with gaming whereas graphic novels may be more effective in a particular sociodemographic group who engage with this genre in other areas of their lives. Ethnic, and age-related, aspects of interventions demand similar sensitive appraisals. If these aspects are not addressed interventions may lose may lose efficacy with some cohorts. Therefore, it is important that the sociohistorical context of interventions and their potential implementation should be addressed. These variables, along with self-efficacy, are hypothesised in our final model as possible moderators (i.e. that they alter the effect size) between the intervention and the likelihood of change in personal abilities and resulting behaviour. In other words, those with high self-efficacy, who are risk takers and whose sociocultural, age and ethnicity profile roughly matches that at which the intervention is aimed, will be more sensitive to the intervention.

Self-efficacy has been retained in the final framework in spite of very few direct references to it in the data. This has been conceptualised, in keeping with Bandura's[198] intentions, as a reflection of confidence that one can exert control over one's situations. Control and the transfer of it into actions is a core aspect of the realist synthesis, and is therefore expected to function in close collaboration with self-efficacy. For this reason, self-efficacy is specified in the model as a moderator and an outcome in itself.

Another moderation effect, shame, is hypothesised in the final framework. It was previously unspecified. Shame would be expected to moderate the relationship between the identification of risk and the effectiveness of the intervention. That is, when shame is high, it will weaken the relationship between the self-identification of risk (and the associated opportunity to create an educationally sensitive moment) and the effects of the intervention. When shame intervenes, individuals may avoid or deny uncomfortable truths, and thus be emotionally and mentally closed to the input and learning that interventions offer.

Finally, intentions, as articulated by Ajzen[200] in the *Theory of Planned Behaviour*, have also not featured explicitly in the data extracted from the synthesis. Readiness to change and motivation have been present in the realist data as contextual factors that trigger intention to change. In our framework refinement, we have discovered that self-identification of risk and the resultant creation of educationally sensitive moments can be important to intervention efficacy. They optimise the potential of an intervention. In our refined framework, intentions act as a bridge between motivations and intervention effectiveness.

In 'testing' or evaluating our framework, further specifications of hypotheses may be developed, for example examining possible mediation effects. With more information, it may be possible to establish critical thinking, reflection and re-identification as mediating factors, explaining or accounting for relationships between interventions and outcomes.

In summary, the explication of behaviour, both to quantify and to mentally re-enact, is an important step in recognising the extent of one's own risk-related sexual behaviour. This should be followed by supportive, skilled facilitation. In turn, this creates an educationally sensitive moment which balances vulnerability with newly identified areas of behaviour and associated patterns of thought reflected by planning and goals. Opportunities to rehearse these behaviours and thinking style are likely to enhance the intervention. The reduction of negative, internalised emotions are central to effective exploration, and action planning is necessary in the transfer of new skills to new safe sexual practices.

Chapter 5 Developing a candidate intervention

Introduction

Using post hoc realist review methods, the previous chapter highlighted intervention components that were indicative of increasing the effectiveness of individual behaviour change interventions among MSM through the delivery of a refined framework and accompanying explanatory theories. The refined framework suggested three explanatory theories relating to interactions of C-M-Os. Together the three theories provide useful direction for developing future interventions in this field. This chapter is concerned with further aspects of intervention development and specification.

The post hoc realist synthesis suggested that ideal interventions should include a number of key elements. It suggested that interventions should start with the client's explication of past risk-related behaviour to objectively quantify and acknowledge previous risk. This should be followed by supportive and skilled facilitation that manages the emotional vulnerability of the client. The interventionist should be non-judgemental and should distinguish between the client's identity and his health-compromising behaviour. Within this interactive element, the interventionist creates an educationally sensitive moment utilising the client's emotional state. The interventionist should focus the client on past thoughts, feelings and behaviour concerning risk and explore alternative patterns of thought and behaviours which are associated with risk reduction. These alternative thoughts should address plans and goals for the future. Opportunities to rehearse thinking styles and behaviours are likely to enhance the intervention through the growth of perceived control and perceptions of self-efficacy. Throughout the interventions the reduction of negative internalised emotions is likely to be important in enhancing effectiveness. Positive, affirmatory interactions should replace negative feelings. Interventions should end with action planning, as this appears important in the transfer of new skills to future sexual practices.

This chapter further examines the available evidence to enhance the development of a candidate intervention. It moves beyond the commissioned research to deliver additional tasks. It focuses on two supplemental areas: (1) further examination and interpretation of the components of interventions as delivered in sequence, to enable the specification of detail required to create an intervention manual; and (2) reassessing the included studies to maximise the potential transferability of available evidence, by critically appraising the social contexts of original studies.

In terms of the first key area, the realist synthesis suggested the importance of attending to the sequential and temporal elements of the interventions. From the client's perspective these are likely to be important, as they shape the client's personal journey through the intervention. They reflect the client's exposure to the range of BCTs and aspects of intervention modality. An evidence synthesis collated for recent NICE guidelines,[76] for example, also highlights the value of perspectives that focus on a wider consideration of intervention content, over and above that provided by the BCT framework in isolation. The evidence synthesis suggests that it is highly likely that there are synergistic effects of individual BCTs working together with cumulative effect. Along these lines, in order to further develop and specify a candidate intervention, it was felt that supplemental analysis should focus on these sequential and potentially cumulative aspects of intervention content and delivery.

The second key area examined here is concerned with a fuller examination of the historical and social context of the interventions. The realist review focused on the microcontext of the intervention as it was delivered. However, in order to further develop an intervention and pre-empt issues relating to the feasibility of potential future studies, it was felt that a wider consideration of cultural and historical issues may provide further useful information and guidance in developing a candidate intervention.

The chapter concludes with the development of a matrix to synthesise the findings from the preceding chapters. It provides a transparent account of how the different types of evidence were utilised within the development of a candidate intervention. The chapter ends with a presentation of the candidate intervention defined by a 'mock' intervention manual.

Method

With regard to the sequential and potential synergistic effects of intervention components, no formal pre-existing assessment tool could be found. Data extraction focused on trying to detail these complex, sequential and potentially cumulative aspects of intervention content. First, each intervention component in turn was noted. Following this, each study was described in relation to the diversity of components used, the incorporation of tools or discrete devices within the intervention, whether or not there was a sense of increasing complexity within the delivery of the intervention across constituent components, how interventions both began and ended, whether or not there was a pattern of increasing personalisation across the intervention and the degree to which within the whole intervention there was a focus on the intrasubjective (i.e. the client thinking about himself presented a major focus for intervention). In addition, given the project team's experience in working with this population, three additional areas of intervention delivery were examined within analysis of the studies: whether or not there was evidence of how the intervention as a whole was imbued with gay identity and community; whether or not it reflected cultural competency with regard to the sexual cultures of MSM (i.e. a set of congruent behaviours, attitudes and policies that come together within intervention delivery to reflect and affirm the sexual cultures of MSM); and the degree to which processes of social influence may have played a tacit, yet still important, part within the research process. The data were examined for patterns and trends in order to provide further direction in the development of the candidate intervention.

One reviewer (PF), with particular expertise in the sociocultural aspects of gay men's sexual cultures, led the assessment of the 11 included studies in relation to factors that may be important with regard to the transfer of evidence to contemporary UK contexts. As no formal tool exists, data relating to cultural and historical contexts were systematically collated regarding the temporal, national, regional and local contexts of research. Such sites were also assessed in relation to their association with gay communities and associated cultures and any information highlighting the role of gay communities within the intervention, either explicit or implicit, was noted. The data were examined for patterns and trends in order to provide enhance the feasibility of delivering a candidate intervention.

To synthesise the evidence from preceding chapters and enable the development of a candidate intervention, key findings were entered into a single table (*Table 14*). This matrix of findings was examined to ascertain patterns in the findings produced by the diverse approaches to evidence synthesis. This matrix enabled a sense of the commonality of findings across the diverse approaches, yet also provided an illustration of where findings relate to only one approach and, indeed, where no available evidence was presented.

Results

Wider synergies across interventions: the ways in which intervention content, delivery and context combine

Table 15 shows that all of the interventions can be thought of as multicomponent interventions, although there are clear differences in the range of components used. For example, Hirshfield *et al.*[104] used the fewest components. All other studies used several tools or exercises. Across the delivery of the multiple components some interventions were designed to increase in complexity[97–103,105,106] and some to have an additional single developmental focus throughout.[97–103,106] Carpenter *et al.*[96] showed no evidence of sequential increases in complexity.

TABLE 14 Evidence metasynthesis and the development of the candidate intervention

Narrative review and meta-analysis	Realist synthesis	Wider synergies across intervention components	Cultural and historical issues in relation to transferability	Other sources of evidence	Ideal candidate intervention
Interventions delivered immediately after testing may be associated with greater treatment effects					Interventions should be delivered immediately after testing
Interventions delivered with face-to-face delivery may be more effective than interventions delivered via the telephone or online					Interventions should be delivered face to face
Interventions which utilise theory-congruent BCTs may be associated with greater treatment effects					Interventions should utilise theory-congruent BCTs
Interventions are effective in reducing HIV infection risk-related behaviour. Unique BCT groups 'goals and planning', 'identity', 'social support' and 'comparative outcomes' were used most often within the interventions	Interventions are likely to be enhanced if they include planning and goal-setting			NICE guidance 2014[210] highlights likely usefulness of BCTs within the goals and planning group	Interventions should use BCTs drawn from the following groups: 'goals and planning', 'identity', 'social support' and 'comparative outcomes'
Interventions are effective in reducing HIV infection risk-related behaviour. Unique individual BCTs most commonly used within the intervention only were 'pros and cons', 'goal-setting', 'social support (emotional)', 'framing and reframing' and 'incompatible beliefs'					Interventions should include the following unique BCTs: 'pros and cons', 'goal-setting', 'social support (emotional)', 'framing and reframing' and 'incompatible beliefs'

continued

TABLE 14 Evidence metasynthesis and the development of the candidate intervention (*continued*)

Narrative review and meta-analysis	Realist synthesis	Wider synergies across intervention components	Cultural and historical issues in relation to transferability	Other sources of evidence	Ideal candidate intervention
Across both intervention and control (usual care), other BCTs are ubiquitous and may be basic components of effective interventions					Interventions should incorporate BCTs relating to 'social support (unspecified)' and 'information about health consequences'
	Interventions are likely to be enhanced if they are multicomponent	Multicomponent interventions are typical and the use of tools within interventions is common			The intervention should be multicomponent and be composed of sequential elements
	Interventions are likely to be enhanced if they begin with risk assessments	Interventions typically begin with a risk assessment			The intervention should begin with a risk assessment exercise
	Interventions are likely to be enhanced if they include third-party involvement	Interventions typically contain a normative peer reference point			The intervention should include a normative peer reference point
	Interventions are likely to be enhanced if they end with a future-facing element	Interventions typically end with a future-facing element			The intervention should end with a future-facing element
	Interventions are likely to be enhanced if they are personalised	Interventions are typically personalised			The intervention should be personalised
	Interventions are likely to be enhanced if they contain intrasubjective elements and address issues such as self-efficacy	Interventions typically contain intrasubjective elements			The intervention should address the intrasubjective and incorporate issues such as self-efficacy. Facilitators should use BCTs such as verbal persuasion about capability

Narrative review and meta-analysis	Realist synthesis	Wider synergies across intervention components	Cultural and historical issues in relation to transferability	Other sources of evidence	Ideal candidate intervention
	Interventions are likely to be enhanced if they are focused on responsibility and capacity	Interventions typically focus on responsibility			The intervention should focus on responsibility and capacity
		Interventions typically demonstrate cultural competency with regard to gay men			The intervention should address cultural competency
	Interventions are likely to be enhanced if they entail a reduction in negative affects (e.g. shame) and increase in positive affects				The intervention should include a reduction in negative affects and an increase in positive affects
	Interventions are likely to be enhanced if they utilise skilled facilitation				The intervention should include skilled facilitation
	Interventions are likely to be enhanced if they are non-judgemental				The intervention should be non-judgemental
	Interventions are likely to be enhanced if they are sensitive to identity. BCTs such as 'identity associated with changed behaviour' may be useful				The intervention should be sensitive to identity. And should utilise BCTs such as 'identity associated with changed behaviour'
	Interventions are likely to be enhanced if they are focus on high-risk men		Interventions are likely to be more feasible if they focus on high-risk men	Health economic arguments	The intervention should focus on high-risk men

continued

TABLE 14 Evidence metasynthesis and the development of the candidate intervention (*continued*)

Narrative review and meta-analysis	Realist synthesis	Wider synergies across intervention components	Cultural and historical issues in relation to transferability	Other sources of evidence	Ideal candidate intervention
			Interventions are likely to be feasible if they occur within cities with large gay populations, but may also be feasible in other geographical areas		Feasibility studies should explore the role of proximity to cities with large gay populations
			Interventions are likely to be more feasible if they include novel aspects within intervention components, this may serve to engage MSM within the intervention		The intervention should include novel aspects within intervention components
			Interventions are likely to be more feasible if they ensure sensitivity to digital and health literacy	Essential to reduce health inequalities	The intervention should ensure sensitivity to digital and health literacy and provide information regarding the complexity of HIV infection risks. Interventions should incorporate the BCT 'information about health consequences'
			Interventions are likely to be effective if they have a clear focus on gay community and identity		A clear focus on gay community and identity

TABLE 15 Sequential components of intervention delivery and cultural and historical issues

Author (year of publication)	Issues		Inferred relevant population characteristics	Component						Synergistic effects within intervention
	Cultural and historical	Tacit normative in relation to sample and delivery		First	Second	Third	Fourth	Fifth	Sixth	
Carpenter *et al.* (2010)[96]	2006; relatively early with respect to the centrality of social media; USA; digitally focused	Recruited through popular gay social media sites; online engagement with system (proxy peer)	Digitally literate; higher-risk MSM; no intervention experience within previous year	Patient engages with intervention software through interactive assessment of HIV infection risk factors and targeted responses based on individual responses	Assessment of readiness to change behaviour	Decisional balance; goal-setting	Communication skills training; sexual safety contracts	Information about correct condom use; condom use myths	Problem-solving exercises; audio narratives; quiz	Diverse components Components are sequentially diverse, structured through the software and interactive in that they deliver tailored responses Little evidence of increasing complexity, but feedback loops provided Intervention incorporates multiple tools throughout Whole intervention is imbued with gay identity and community, with the recruitment of participants through gay social media Sexual health is presented within the context of wider health Whole intervention provides strong injunctive norms regarding sexual safety Some focus on intrasubjective Client is responsible for behaviour change through their motivation to change

continued

TABLE 15 Sequential components of intervention delivery and cultural and historical issues (*continued*)

Author (year of publication)	Issues		Inferred relevant population characteristics	Component						Synergistic effects within intervention
	Cultural and historical	Tacit normative in relation to sample and delivery		First	Second	Third	Fourth	Fifth	Sixth	
Christensen *et al.* (2013)[97]	2012; within the era of the mass use of social media; USA; digitally focused	Recruited through popular gay social media sites; sex positive; ethnically diverse; focus on normalising same-sex desire	Digitally literate; games literate; young gay men; higher-risk MSMs	Customise avatar	Flirt with other partners at house party; make decisions about sex and alcohol	Potential sex partners apartment; initiate conversation about safe sex and condom use; feedback given instantly if player makes a risky choice	Recap of players virtual behaviour and link to real-life consequences	Virtual nightclub in which decision points are more complex		Diverse components Intervention consists of multiple tools Complexity and challenge of intervention increases throughout the components Feedback provided Clear focus on shame and emotions Sexual health is presented within the context of wider health Whole intervention is imbued with gay identity, community and demonstration of gay cultural competency Minimal focus on intrasubjective Behaviour change achieved through skill acquisition

Author (year of publication)	Issues		Inferred relevant population characteristics	Component						Synergistic effects within intervention
	Cultural and historical	Tacit normative in relation to sample and delivery		First	Second	Third	Fourth	Fifth	Sixth	
Coffin *et al.* (2014)[98]	2010–12; San Francisco, CA, USA; episodic drug use	Drug use as normative	Relatively complex needs and vulnerable population; commercial venues and those using ethnicity-based community organisations; major international 'gay' city; strong community norms and identities; SJQ comes from other MSMs' self-justifications	Patient recalls risk event, focus on personal relevance and specificity	SJQ administered, focus on cognitive dissonance and priming self-justifications; SJQ comes from other MSMs' self-justifications	Counsellor facilitates participant to identify which justification led to risky sexual behaviour	Patient explores strategies to avoid high-risk situations in the future	Patient reframes self-justifications to clarify objective risk	Patient generates alternative self-statements that may reduce sexual risk in the future	Diverse components Components are sequentially diverse and tightly structured A sense of the intervention increasing in complexity through the delivery of sequential components and having a single developmental focus throughout Intervention incorporates tools The intervention is deeply personalised and understands the determinants of risk as context bound, emotional and cognitive The intervention uses the distinction between sexual decision-making in sexual vs. non-sexual situations. It also provides a framework that categorises attributions of causality dichotomously as either socially acceptable or unacceptable (i.e. an invalid self-justification) Whole intervention is imbued with gay identity and community, with the recruitment of participants through gay social media Whole intervention focuses on a strong moral norm inherent within the idea of self-justifications (rather than rational reasons for risk-related behaviour) Major focus on intrasubjective (client is understood to be primary cause and solution to reducing HIV infection risk-related behaviour) Client is responsible for behaviour change through their motivation to change

continued

TABLE 15 Sequential components of intervention delivery and cultural and historical issues (*continued*)

Author (year of publication)	Issues		Inferred relevant population characteristics	Component						Synergistic effects within intervention
	Cultural and historical	Tacit normative in relation to sample and delivery		First	Second	Third	Fourth	Fifth	Sixth	
Dilley *et al.* (2011);[99] and Dilley *et al.* (2007)[100]	USA	Peer counsellors; PCC is peer focused and elicited	Repeat testers; assumed HIV literate, as already engaging with services	Patient recalls risk event, focus on personal relevance and specificity	SJQ administered, focus on cognitive dissonance and priming self-justifications; PCC comes from other MSMs self-justifications	Counsellor elicits sequential, social and emotional context of risk event; for example events, activities, mood, location, levels of attraction, alcohol, drugs, communication between partners about HIV and aspects of sex, sexual communication, body language, use of alcohol and drugs and estimated levels of risk	Focus on recall of HIV-related thinking within event and associated attributions; counsellor identifies self-justifications	MSM formulates plans for the future in terms of other similar situations via the avoidance of self-justifications		Multiple components Components are sequentially diverse and tightly structured Intervention incorporates tools: SJQ, reflective session, forming plans A sense of the intervention increasing in complexity through the delivery of sequential components and having a single developmental focus throughout The intervention is deeply personalised and understands the determinants of risk as context bound, emotional and cognitive Elements of the intervention are oriented towards complexity of contemporary risk management Future-facing action plan tailored to the patient (this is also provided via control within the Dilley *et al.* studies[99–101]) The intervention uses the distinction between sexual decision-making in sexual vs. non-sexual situations. It also provides a framework that categorises attributions of causality dichotomously as either socially acceptable or unacceptable (i.e. an invalid self-justification) Whole intervention is imbued with gay identity and community, with the recruitment of participants through gay social media

Author (year of publication)	Issues		Inferred relevant population characteristics	Component						Synergistic effects within intervention
	Cultural and historical	Tacit normative in relation to sample and delivery		First	Second	Third	Fourth	Fifth	Sixth	
										Whole intervention focuses on a strong moral norm, inherent within the idea of self-justifications (rather than rational reasons for risk-related behaviours) Major focus on intrasubjective (client is understood to be the primary cause and solution to reducing HIV infection risk-related behaviours) Client is responsible for behaviour change through their motivation to change
Dilley *et al.* (2002)[101]	1997–2000; period immediately following ART; San Francisco, CA, USA	Exclusion of people who injected drugs	Repeat testers; high-risk MSM; major international 'gay' city, strong community norms and identities; SJQ comes from other MSMs self-justifications	Client fills in SJQ with knowledge of what will happen; tacit appraisal of injunctive and descriptive social norms	Counsellor receives a summary of clients SJQ	Introduction; sex positive; personal responsibility	Recent story addressing most recent high-risk UAI in detail; focus on specific thoughts and feelings associated with risk	Critical examination in which counsellor notes self-justifications not mentioned in SJQ; client and counsellor critically examine self-justifications; agreements made concerning future management of similar situations	Closure; counsellor-facilitated reflective focus on the session	Components are sequentially diverse and tightly structured Intervention incorporates tools The intervention is deeply personalised and understands the determinants of risk as context bound, emotional and cognitive The intervention uses the distinction between sexual decision-making in sexual vs. non-sexual situations. It also provides a framework that categorises attributions of causality dichotomously as either socially acceptable or unacceptable (i.e. an invalid self-justification) Major focus on intrasubjective (client is understood to be primary cause and solution to reducing HIV infection risk-related behaviour)

continued

TABLE 15 Sequential components of intervention delivery and cultural and historical issues (*continued*)

Author (year of publication)	Issues		Inferred relevant population characteristics	Component						Synergistic effects within intervention
	Cultural and historical	Tacit normative in relation to sample and delivery		First	Second	Third	Fourth	Fifth	Sixth	
Eaton *et al.* (2011)[102]	2009; serosorting focus, contemporary with high ecological validity; recruited black MSM living in high-prevalence cities	Peer counsellors used tacit injunctive norms; graphic novel provides a tacit descriptive/moral norm	High-risk MSM; paid for participation in study motivation issue; 40% of eligible participants did not show for appointments	Graphic novel; personally relevant narrative (serosorting)	Face-to-face interaction with peer counsellor in which joint problem-solving occurred	Sexual network diagram of character in novel presented	Participants create and use their own sexual network diagram as a guide to forming a plan; sexual network diagram of character in novel; own network created and compared with character in novel; used to facilitate discussion	MSM reviewed own conduct, formulate ways they could do things differently in the future; increases in condom use; reductions in partner numbers and acts; alternatives to UAI, disclosure issues, testing history issues; created a menu of harm reduction options by weighing the relative costs and benefits of each and deciding on an optimal choice		Diverse and multiple components Components are sequentially diverse and tightly structured Components in general build in complexity and have a single developmental focus throughout Intervention incorporates multiple tools: graphic novel, sexual network diagrams and action plan Gradually sensitise to the patient (becomes increasingly personal) Whole intervention is imbued with normative influence (injunctive, descriptive and tacit moral norms) Whole intervention is flavoured with an understanding of the person as embedded within a social context yet focuses on personal agency therein, with a clear focus on making complex yet informed decisions Whole intervention is oriented towards complexity of contemporary risk management Whole intervention is imbued with gay identity and community, with the recruitment of participants through gay social media Cocreate a future-facing action plan tailored to the patient

Author (year of publication)	Issues		Inferred relevant population characteristics	Component						Synergistic effects within intervention
	Cultural and historical	Tacit normative in relation to sample and delivery		First	Second	Third	Fourth	Fifth	Sixth	
										Medium focus on intrasubjective (client is understood to be primary cause and solution to reducing HIV infection risk-related behaviour) Client is responsible for behaviour change through their motivation to change
Hao *et al.* (2012)[103]	2008–9; Nanjing, China; prevalence around 5%	Men recruited via respondent-driven sampling, so tacit descriptive and injunctive normative influence; video focuses on normative influence, injunctive and speaks to identity and sense of community (i.e. protecting partners); cloth bracelet functions as a signifier of intervention participation and will represent a norm within sexual interaction	MSM reporting anal sex per se, not high-risk subpopulation; 0.03% of eligible participants did not show up for appointments, which has to do with timing of the randomisation and intervention	SVCT followed by 6-minute video of Chinese HIV-positive man; theory and expert panel informed script based on HIV-positive man's experience in which he also persuades patients to protect themselves and their partners from HIV infection	Enhanced post-test counselling, which focused on stages of change and MI approach; this was about the patient's personal circumstances; it focused on motivating men to use condoms consistently and creating mental conflicts	An action plan was created by the participants	Given a cloth bracelet as a reminder of safer sex			Varied components are sequentially diverse and tightly structured Components in general build in complexity and have a single developmental focus throughout Gradually sensitised to the patient (becomes increasingly personal) Intervention incorporates tools: testing process, video and action plan Intervention is imbued with normative influence (injunctive, descriptive, and tacit moral norms) – within recruitment and video Whole intervention is imbued with gay identity and community, with the recruitment of participants through gay social media Future-facing action plan tailored to the patient Medium focus on the intrasubjective Client is responsible for behaviour change through their motivation to change

continued

TABLE 15 Sequential components of intervention delivery and cultural and historical issues (*continued*)

Author (year of publication)	Issues			Component						Synergistic effects within intervention
	Cultural and historical	Tacit normative in relation to sample and delivery	Inferred relevant population characteristics	First	Second	Third	Fourth	Fifth	Sixth	
Hirshfield *et al.* (2012)[104]				Watch video relating to the positive and negative modelling of HIV disclosure; focus on critical thinking and decision-making						Limited number of components Intervention is minimal in comparison to others A single narrative device is expected to elicit a response within the recipient Intervention consists of tools (video extracts) Intervention has no personalisation or tailoring Intervention addresses the complexity of contemporary HIV infection risk reduction Whole intervention is imbued with gay identity and community, with the recruitment of participants through gay social media Minimum focus on intrasubjective Behaviour change occurs through skill acquisition

Author (year of publication)	Issues		Inferred relevant population characteristics	Component						Synergistic effects within intervention
	Cultural and historical	Tacit normative in relation to sample and delivery		First	Second	Third	Fourth	Fifth	Sixth	
Parsons *et al.* (2014)[105]				Baseline data concerning psychosocial characteristics	Timeline (follow-back calendar) to create calendar of sex and substance use for previous 30 days; provide information about club drugs and HIV risk	In relation to either substance use or sex; engagement with clients readiness to change; focus on increasing willingness to change; completion of a plan for change including goals and potential barriers	In relation to either substance use or sex; engagement with clients readiness to change; focus on increasing willingness to change; completion of a plan for change including goals and potential barriers; staging ruler and decisional balance tool examining pros and cons of behaviour change	Review and addressing of progress in relationship to ambivalence, readiness for change, affirmation of gains and commitment; re-examination of decision balance and goals	Final review and revision of goals and change plan; emphasis on self-efficacy for attaining goals; ongoing discussion of relationship between substance use and high-risk sex; and reflection on wider resources and referrals available	Multisession Diverse and multiple components Intervention incorporates multiple tools throughout The intervention is deeply personalised and understands the determinants of risk as context bound, emotional and cognitive and pharmacological Intervention is imbued with normative influence (injunctive, descriptive, and tacit moral norms) – within recruitment and delivery (counsellor assessment of PFR) A sense of the intervention increasing in complexity through the delivery of sequential components and having a dual developmental focus throughout Within intervention a future-facing action plan tailored to the patient is created Whole intervention is imbued with gay identity and community, with the recruitment of participants through gay social media Some focus on intrasubjective (client is understood to be primary cause and solution to reducing HIV infection risk-related behaviour) Client is responsible for behaviour change through their motivation to change

continued

TABLE 15 Sequential components of intervention delivery and cultural and historical issues (*continued*)

Author (year of publication)	Issues		Inferred relevant population characteristics	Component						Synergistic effects within intervention
	Cultural and historical	Tacit normative in relation to sample and delivery		First	Second	Third	Fourth	Fifth	Sixth	
Picciano *et al.* (2007)[106]				Collection of personal data regarding knowledge of HIV, sexual activity, substance use patterns in relation to sexual risks, intentions to use condoms, rationale for sexual decisions – benefits and losses associated with condom use, perceived self-efficacy for avoiding HIV infection risks; feedback on personal behaviour	Emphasis on personal responsibility	Clear advice to change	Menu of alternative behaviours	Therapist empathy	Facilitation of optimism to change	Varied components Components are sequentially diverse and tightly structured Intervention incorporates tools: the PFR data Components in general build in complexity and have a single developmental focus throughout Intervention is imbued with normative influence (injunctive, descriptive, and tacit moral norms) within recruitment and delivery (counsellor assessment of PFR) Future-facing action plan tailored to the patient The intervention is deeply personalised and understands the determinants of risk as context-bound, emotional and cognitive Whole intervention is imbued with gay identity and community, with the recruitment of participants through gay social media Minimal, oriented towards complexity of contemporary risk management Some focus on the intrasubjective (client is understood to be primary cause and solution to reducing HIV infection risk-related behaviour) Client is responsible for behaviour change through their motivation to change

ART, antiretroviral therapy; PFR, personal feedback report; SJQ, self-justification questionnaire; SVCT, standard voluntary counselling and testing.

Likewise, the interventions typically followed a similar pattern, with the first component of the intervention being different from the components that followed. An exception is the study by Hirshfield *et al.*[104]

Many of the interventions begin with the individual completing a risk assessment tool that focuses, either explicitly or implicitly, on assessing the individual's risk relative to his peers. Carpenter *et al.*,[96] for example, report the use of an interactive assessment of HIV risk factors. Although starting the process of personalising risk, this component also tacitly offers descriptive norms of peers. In this way, a process of social influence may occur. Both Coffin *et al.*[98] and Dilley *et al.*[99–101] reported that participants were required to complete a self-justification questionnaire at the start of the intervention. As well as being the foundation of personalisation, this intervention component again serves to tacitly offer descriptive norms regarding peers and again indicates the potential of social influence. Picciano *et al.*[106] report the collection of personal data regarding a variety of risks, and again tacit peer norms may be activated through this activity. However, Parsons *et al.*[105] report the use of a timeline follow-back calendar which, while personalising the intervention, does not offer any normative reference point. The intervention described by Christensen *et al.*[97] starts with the client customising an avatar and again is distinct from this pattern within the interventions examined.

In terms of how interventions end, again there is a clear pattern, with the majority of interventions including towards their end components that are clearly focused on clients' future behaviour, for example requiring clients to generate alternative self-statements that may reduce sexual risk in the future;[98] to come to an agreement with the therapist concerning future management of similar situations;[101] or to formulate plans for the future in terms of other similar situations via the avoidance of self-justifications.[99,100] In the study by Eaton *et al.*[102] the interventionist and client generated a risk reduction plan. Similarly, the intervention used by Hao *et al.*[103] required the client to create an action plan. The intervention evaluated by Picciano *et al.*[106] ended with the interventionist facilitating optimism that the cient can effect change. In contrast, the interventions used by Carpenter *et al.*,[96] Christensen *et al.*,[97] Parsons *et al.*[105] and Hirshfield *et al.*[104] did not end with a future-facing element.

Several of the interventions contained elements that ensured they were personalised and tailored to the clients' specific needs.[97–102,105,106] The components of the intervention described by Hao *et al.*[103] became increasingly personal over time, although the intervention had a more 'generic' end point (i.e. patients were given a bracelet to wear). In contrast, the intervention described by Hirshfield *et al.*[104] was not personalised at all. Tailored personal feedback was provided in the online interventions evaluated by Carpenter *et al.*[96] and Christensen *et al.*,[97] and personalised feedback was to some extent provided in situ through those interventions that utilised self-justifications questionnaires, such as those evaluated by Coffin *et al.*[98] and Dilley *et al.*[99–101] In Parsons *et al.*'s[105] multisession intervention, there was an opportunity for the interventionist to provide feedback to the client regarding progress between sessions.

The extent to which the intervention and its components focused on intrasubjective aspects of the client (i.e. the clients' awareness of their own thinking patterns) varied across the studies. It seems likely that the personalisation identified earlier in this section has a synergistic effect, securing a primed focus on the intrasubjective elements of interventions. Hirshfield *et al.*[104] and Christensen *et al.*[97] report a minimal focus on the intrasubjective. Carpenter *et al.*,[96] Eaton *et al.*,[102] Hao *et al.*,[103] Parsons *et al.*[105] and Picciano *et al.*[106] describe some focus on the intrasubjective. Coffin *et al.*[98] and Dilley *et al.*[99–101] report a major focus on the intrasubjective. In this last group of studies there is an explicit focus on clients identifying patterns in their thinking, which is associated with how they attribute the causal determinants of their risk-related behaviour (i.e. self-justifications). Similarly, most interventions can be characterised by their focus, either explicitly or implicitly, on how they understand and promote the clients' *responsibility* in motivating themselves towards maintaining behaviour change. In other words, it is the client who needs to change his motivation, thinking and behaviour.[96,98–103,105,106] In contrast, both Christensen *et al.*[97] and Hirshfield *et al.*[104] placed a distinct focus on clients' deficiencies in terms of their lack of specific skills (i.e. risky decision-making and HIV status disclosure).

Finally, intervention components were examined in relation to inferred characteristics. Although the study authors do not describe them as key intervention components, these inferred aspects may be active parts

of the intervention nonetheless. For example, it seems likely that several of the interventions demonstrate a high degree of gay cultural competency. Although this is important for engagement with trial design (e.g. recruitment and follow-up), it is also important with regard to social influence and the tacit description of both descriptive and injunctive social norms. Cultural competency and tacit social influence were potentially part of all the interventions, for example through a virtual focus on typical locations where MSM may meet, such as representations of house parties and night clubs.[97] Similarly, the use of self-justification questionnaires can be thought of as indicative of commonplace scenarios and dilemmas faced by the MSM population,[98–101] particularly when they have been tailored to the local population and their needs.[98] The intervention evaluated by Eaton *et al.*[102] utilised a graphic novel demonstrating the complexity of HIV risk management in what the authors describe as an informative and non-intimidating manner. Although the authors do not report details of the graphic novel, it seems likely that the visual images were contemporary and were designed to specifically focus participants on engagement with the intervention issues (i.e. serosorting). The intervention evaluated by Hao *et al.*[103] incorporated a video example of a local peer who had become infected with HIV, whereas the video clips used by Hirshfield *et al.*[104] are described as depicting a peer context that related to drug use in the MSM community. Picciano *et al.*[106] also focused on the club drugs and sex. Thus, a pattern is apparent, with all interventions demonstrating cultural competency.

In summary, interventions tend to comprise multiple components, delivered with increasing complexity and focusing on a single developmental trajectory. The interventions display a pattern, with a first intervention component that is different from subsequent components. Moreover, the majority of interventions begin with a personal assessment of risk, often conducted with little initial interaction with the interventionist. This assessment of personal risk usually includes exposure to relative risks faced by peers. Similarly, the majority of interventions end with a component that is focused on the future, often involving setting goals or agreeing an action plan. The majority of studies evaluate interventions that are personalised and tailored to clients' individual needs. The majority of studies evaluate interventions which, following a degree of personalisation, have a distinct focus on intrasubjective elements with the aim of getting clients to take responsibility for their behaviour change and to identify potential ways to achieve it. The majority of studies evaluate interventions that can be seen to demonstrate cultural competency with respect to the sexual environments and the concomitant dilemmas faced by MSM at the time of their implementation.

Contextual factors and future intervention development

Table 15 shows that all studies but one were conducted in the USA.[103] Thus, there are key cultural differences between the UK and the wider cultural contexts in which intervention evaluations were conducted. These may shape the future feasibility of intervention evaluation. It is also worth noting that many studies were conducted in large cities with particularly vibrant gay communities, such as San Francisco[98–101] and New York.[105] Picciano *et al.*[106] collected data in a number of smaller states and reported a retention of 80% in both arms of their trial. This is indicative of a firm commitment to the research project and such engagement may be attributable to the relative novelty of behavioural research relating to reducing HIV infection risk-related behaviours in these smaller city contexts. Although it may appear to be more feasible to conduct large trials in major gay cities, this also appear to be achievable in other areas.

The studies examined were also conducted at different times, which may limit their contemporary relevance. For example, Dilley *et al.*[101] conducted their study in the period immediately following the widespread availability of antiretroviral therapy (1997–2000), whereas Picciano *et al.*[106] collected data between 2002 and 2004 and delivered the intervention by telephone. This may seem outdated now but the trial pre-dated the widespread use of the internet and mobile phones.

In terms of the relevance of more contemporary issues, Carpenter *et al.*,[96] who collected data in 2006, and Hirshfield *et al.*,[104] who collected data in 2008, both utilised social media before it was entrenched and normalised in communities of MSM, and before it utilised the global positioning system (GPS). Parsons *et al.*[105] collected data between 2007 and 2010. Hao *et al.*[103] collected data between 2008 and 2009, and Eaton *et al.*[102] collected data in 2009. Their study focused on serosorting and some of the complexity of HIV risk reduction. It firmly addressed HIV risk in ways that were not limited to condom use. Coffin *et al.*[98] collected data between

2010 and 2012 and the study focused on episodic drug use, again chiming with contemporary issues in gay cultures. Christensen *et al.*[97] collected data in 2012 and based their intervention on an interactive game in an era in which the social media had become a major forum for the sexual conduct of MSM. Arguably, at the time of their delivery these interventions all contained relatively novel aspects.

All of the studies included in the review were facilitated by, and imbued with, the strong and tacit presence of gay community. Processes of social influence such as the role of social norms, both descriptive and injunctive, are highly likely to have played a part in the feasibility of studies (e.g. in relation to issues of engagement and retention). Study participants were recruited through gay social media sites,[96,97,104] gay commercial venues[98,105,106] and gay printed media.[105,106] Moreover, in one study, respondent-driven sampling was used in recruitment.[103] These factors may be significant in increasing the feasibility of conducting a trial among MSM.

Across the included studies there are also a number of issues relating to the subpopulations under study that may be important in considering the development and delivery of a candidate intervention. Assumptions of digital literacy and a certain level of material wealth shape the samples used within the studies that utilise online environments to deliver interventions.[96,97,104] Given the differential time frames of their implementation and their relation to the growth in the popularity of the social media as a means of arranging sexual conduct between MSM, it is likely that particular biases, such as digital literacy, differ across these three studies. Socioeconomic factors and tacit skill sets, such as digital literacy and access to computers and mobile devices, should be considered as shaping the feasibility of evaluating interventions within populations of MSM.

In addition, the majority of interventions were trialled in populations of high-risk MSM, rather than the general population of MSM, with the studies of Hao *et al.*[103] and Hirshfield *et al.*[104] being the only exceptions. This distinction may well be important, as it reflects differences in the intrinsic motivation to engage with intervention evaluation that may include time-intensive commitment such as follow-up assessments. Some studies recruited men from existing HIV infection testing services,[100,101] whereas others recruited samples from existing health and social services for MSM.[98,102,105]

In summary, patterns within the social and historical context of interventions suggest that shared collective identity may be important in relation to engagement with research designs (e.g. recruitment and follow-up). Sensitivity to gay identity and processes of social influence may be important factors in harnessing the acceptability and feasibility of research designs. Moreover, aside from any health economic arguments that might be important in terms of targeting those at higher risk, acceptability and feasibility may be maximised in study designs that target higher-risk MSM who may be more intrinsically motivated to engage within studies than those at lower or no risk. Innovation, or a reflection of 'contemporary' issues, may also be important in terms of the acceptability and feasibility of future intervention design, evaluation and engagement.

Matrix of key findings

Table 14 provides a matrix of results across the reports constituent parts. It shows the results of the narrative review, the exploratory meta-analyses and the post hoc realist review and supplemental issues noted in this chapter. It lists evidence informed aspects of a candidate intervention.

In summary, it shows that a candidate intervention should be delivered immediately after testing and should be delivered face to face. Interventions should be delivered by people with skilled facilitation techniques. The intervention should be non-judgemental, and include a reduction in negative affect and an increase in positive affect. It should focus on high-risk men and, if possible, demonstrate some novelty or capture contemporary issues affecting gay men and their sexual cultures. It should be sensitive to issues of identity and contain a clear focus on gay community. The intervention should demonstrably deliver a sense of cultural competency.

Interventions should be multicomponent and be composed of sequential elements. They should begin with a risk assessment exercise, include a normative peer reference point and the use of discrete tools, and end with a future-facing element. A candidate intervention should be personalised and address the intrasubjective (i.e. include elements that encourage clients to consider their own thinking as part of how

they should change their behaviour). Interventions should focus on encouraging a sense of individual responsibility but be mindful of issues concerning individuals' capacity, for example paying particular attention to issues of health and digital literacy.

In terms of the specific content, interventions should utilise theory-congruent BCTs if possible, and 'goals and planning', 'identity', 'social support' and 'comparative outcomes'. They should utilise 'pros and cons', 'goal-setting', 'social support (emotional)', 'framing and reframing' and 'incompatible beliefs'. Given the ubiquitous presence of 'social support (unspecified)' and 'information about health consequences' in both interventions and usual care, these may also be important BCTs to include in any intervention.

The development of a mock intervention manual

The expert events detailed within the following chapter focused on ways to improve a candidate intervention by identifying potential implementation issues. Thus, for the expert events to work, the intervention had to feel both real and as manageable as possible within the UK context. A mock intervention manual and a one-page summary of the intervention were created for use in the expert events and to act as a tool to focus experts on issues of implementation.

The format and structure of the intervention manual in the Dilley *et al.*[100] study was used to populate key sections of the intervention manual using the findings from the matrix of results illustrated in *Table 14*. In this way, a detailed six-page intervention manual was produced (see *Appendix 5*). In addition, a one-page summary of the intervention, 'How to stay HIV negative', was also created (*Box 1*). When little or no evidence existed to shape the mock intervention summary or manual, pragmatic decisions were made to include criteria which were then explored within the expert events. As an example, we provided a definition of to whom the intervention would be offered. Similarly, drawing on the original commissioning brief the intervention was given the name of 'How to stay HIV negative'.

Appendix 6 provides an illustration of the evidence source underpinning the sequential components and specified content of the candidate intervention.

BOX 1 Summary of 'How to stay HIV negative'

Core elements

Core elements are the essential parts of an intervention. They cannot be overlooked or modified. BCTs are listed as the irreducible active ingredients of the intervention content.

1. Peer-oriented visual aid, which details the complexity of contemporary HIV risk (emotions and feelings, serosorting, barebacking, PrEP, TASP and recreational drug and alcohol use) ('information about health consequences').
2. The provision of one-on-one counselling that focuses on the clients' perceptions of the determinants of a single high-risk event ['social support (unspecified)'].
3. A client-centred appraisal of personal risk using the visual aid to compare with the high-risk event and examine clients' decision-making processes ('problem-solving and social comparison').
4. A practitioner- and client-focused assessment and reinforcement of motivation to change, through retrospective analysis of the ways the client could have done things differently. This is achieved by weighing up the pros and cons of alternative behaviours. The practitioner guides the client to articulate how he would do things differently in the future in order to stay HIV negative ('pros and cons', 'problem-solving', 'framing/reframing' and 'incompatible beliefs').
5. Guide the client to articulate and commit to a specific action plan, persuade them about their capability and focus them on their identity as someone who used to take HIV risks but is now 'HIV negative' ('action planning', 'identity associated with changed behaviour' and 'verbal persuasion about capability').

Chapter 6 Optimising an evidence-informed intervention through expert events

Introduction

The previous chapters have detailed the best available evidence presented as a narrative review, meta-analyses, realist synthesis and the synthesis of findings to date. In the previous chapter, these were combined in order to develop a candidate intervention, which can be thought of as optimal and evidence informed. In this chapter this intervention is further refined through expert events, which sought to consider its translation into the existing service provision in the UK. Medical Research Council guidance on the development, evaluation and implementation of complex interventions notes that insufficient consideration of intervention development, piloting and assessment of issues of implementation can result in weak interventions that are difficult to evaluate and implement.[78]

Aims of the expert event

- Identify major systemic and psychosocial barriers to, and facilitators of, implementing the optimal intervention in key settings.
- Identify elements of the optimal intervention that should be refined prior to feasibility testing in order to detail an implementable candidate intervention.

Our initial protocol specified that the project advisory group (PAG) would be sent the matrix of results from the narrative review and meta-analyses. In turn, members of the PAG would be asked to digest and consider the implications for contemporary and future service provision. Using a specified design brief and pro forma, each would then be asked to develop an evidence-based individual motivational behaviour change intervention for HIV-negative men concerning 'How to stay HIV negative'. Given the limitations of the evidence included in the narrative and meta-analyses (see *Chapters 2* and *3*), the project team instead prepared an evidence-informed candidate intervention (see *Chapter 5*) in advance and used two expert events to focus on how best to operationalise and implement this in practice: a key stage in the development of complex interventions.

We developed the dual theoretical synergy (DTS) method to examine expert opinion on the candidate intervention. The PAG, public and patient involvement (PPI) members, and a range of experts in implementing and delivering individual-level interventions to MSM were invited to attend all-day events during which the normalisation process theory (NPT) and the theoretical domains framework (TDF) were used to examine, respectively, systemic and psychosocial barriers to, and facilitators of, the implementation of the candidate intervention. The benefit of the method we developed is in the assessment of how individual psychosocial issues are embedded in the systemic and contextual.

Normalisation process theory is a theoretical construct designed to assess issues of implementation and the ways in which an intervention could become part of routine practice, that is, normalised.[211] NPT can be used in intervention development, in optimising evaluation and in planning implementation.[211] Here, it was used to help participants assess how the intervention relates to what people actually do and how they work.[212] The TDF is an integrative theoretical framework that contains 14 domains reflective of the behaviour change processes required for implementation of an intervention (*Table 16*).[213] TDF can be used in intervention development to identify the barriers to, and facilitators of, behaviour change that would have to be addressed, and the BCTs (i.e. intervention components) that could be used to account for and capitalise on these.[214] Here, it was used to help participants to think through the difficulties that they or their staff might encounter in delivering the hypothetical intervention and to collate issues that would have to be addressed in intervention manualisation, or through the training provided to those delivering the intervention.[214]

TABLE 16 Normalisation process theory: constructs and domains

Construct ($n = 4$)	Domain ($n = 16$)	Aspirational statement
Coherence	Differentiation	Participants are able to distinguish the intervention from current ways of working
	Communal specification	Participants collectively agree about the purpose of the intervention
	Individual specification	Participants individually understand what the intervention requires of them
	Internalisation	Participants can construct potential value of the intervention for their work
Cognitive participation	Initiation	Key individuals drive the intervention forward
	Enrolment	Participants agree that the intervention should be part of their work
	Legitimation	Participants buy in to the intervention
	Activation	Participants can continue to support the intervention
Collective action	Interactional workability	Participants can perform the tasks required by the intervention
	Relational integration	Participants maintain their trust in each other's work and expertise through the intervention
	Skill set workability	The work of the intervention is appropriately allocated to participants
	Contextual integration	The intervention is adequately supported by its host organisation
Reflexive monitoring	Systematisation	Participants are able to access information about the effects of the intervention
	Communal appraisal	Participants can collectively assess the intervention as worthwhile
	Individual appraisal	Participants can individually assess the intervention as worthwhile
	Reconfiguration	Participants can modify their work in response to their appraisal of the intervention

Methods

Experts in both Scotland and England were invited to take part in an intensive full-day workshop, split into three sessions:

1. systemic barriers to, and facilitators of, implementation
2. psychosocial barriers to, and facilitators of, implementation
3. contextual barriers to, and facilitators of, implementation.

One event was held in Glasgow and another in London to include perspectives on the different health systems in Scotland and England. *Table 17* provides an illustration of the diverse expertise utilised within the expert events.

Participants

Overall, 24 experts attended the events (15 in Glasgow and eight in London): 18 were working directly with MSM in some capacity and nine self-identified as gay men. Our experts were primarily employed by the NHS ($n = 19$), with a further four from third-sector organisations and one PPI representative in

TABLE 17 Expert event participants: areas of expertise

Job title	Number of experts
Health improvement/promotion specialist	8
Sexual health advisor	8
Psychologist	4
Sexual health consultant/doctor	2
PPI representative	1
Other	1
Area of expertise	
Clinical services, including HIV infection testing	12
Counselling	10
HIV infection prevention	7
Support for people living with HIV	4
Public/sexual health improvement	3
Other	2

attendance. An overview of the job title and areas of expertise of the attendees is shown in *Table 17*. Please note that some had expertise in more than one area.

As part of the preparation for the event, participants were sent (in advance) a one-page summary of the candidate intervention and a five-page draft intervention manual describing its unique detailed features (see *Box 1* and *Appendix 5*). At the start of the workshop, participants were also given an overview of the theoretical basis for the intervention, the key findings of the project to date, the intervention development process that shaped the candidate intervention (see *Chapter 5*), six steps of delivering the candidate intervention, and the desired outcome of the expert event. Participants were given the opportunity to ask questions to ensure that they had an in-depth understanding of the candidate intervention prior to reviewing the potential barriers to, and facilitators of, implementing it.

Participants worked in small groups (three held in Glasgow and two in London, with a changeover in group membership between sessions). Facilitated group exercises were used to examine (1) systemic barriers to, or facilitators of, using the 16 domains of NPT; (2) psychosocial barriers to, or facilitators of, using the 14 domains of the TDF; and (3) three further context-specific domains related to commissioning and mode of delivery of this particular intervention. At the Glasgow event, experts were taken through session 2 on the TDF first, followed by the session on NPT. Feedback suggested that the order was counterintuitive and was reversed for the London event 3 days later. The results are presented in the latter order. Each of the 33 domains was examined individually, through rapid, focused and tightly facilitated group discussion.

Session 1: normalisation process theory

Session 1 asked participants to consider the systemic barriers to, or facilitators of, implementing the candidate intervention, with a particular focus on how feasible the intervention would be in the current health-care system, using NPT.[211] By encouraging participants to consider how the intervention related to the 16 NPT domains, we were able to assess the likelihood of it being implemented and, most importantly, what might have to be changed to increase this likelihood.

The 16 domains of NPT are split into four constructs:

1. coherence: understanding what the intervention is (domains 1–4)
2. cognitive participation: understanding who in an organisation would have to be involved, how they will be enrolled, engage with and support the intervention (domains 5–8)
3. collective action: understanding how the actions of those involved will promote or inhibit the intervention from working (domains 9–12)
4. reflexive monitoring: understanding impact via formal and informal appraisal of the intervention (domains 13–16).

Experts were guided through the 16 domains and presented with each associated 'aspirational' statement that defines the domain,[212] then asked to consider a series of related questions to help them to think through the issues and how the intervention might need to change[211] (see *Table 16*).

Session 2: theoretical domains framework

To assess the psychosocial barriers to, and facilitators of, implementing the intervention, participants were asked to discuss how likely it was that psychosocial issues would influence their staff in delivering the intervention, using the TDF.[213] For each of the 14 TDF domains (illustrated and explained in *Table 18*), we presented the concept or domain that was to be discussed and asked the experts to discuss the barriers to, or facilitators of, implementing the intervention in relation to this.

Session 3: contextual barriers and facilitators

The final session addressed three further context-specific domains related to commissioning and mode of delivery: cost, settings and new technologies. Doing this enabled us to ensure that the DTS analysis

TABLE 18 Theoretical domains framework: domains and explanatory statements

Domains	Explanatory statement
Knowledge	An awareness of the existence of something
Skills	Ability or proficiency acquired through practice
Professional roles/identity	Coherent set of behaviours and personal qualities of an individual in a work setting
Beliefs about capabilities	Acceptance of the truth or validity of an ability that a person can put to constructive use
Optimism	Confidence that things will happen for the best or that desired goals will be obtained
Beliefs about consequences	Acceptance of the truth or validity about outcomes of a behaviour
Reinforcement	Increasing the probability of a response by arranging a dependent relationship between the response and a contingency
Intentions	Conscious decision to perform a behaviour or act in a certain way
Motivation and goals	Representation of outcome that individual wants to achieve
Memory and decision processes	Ability to retain information, focus selectively and choose between two or more alternatives
Environmental context and resources	Any circumstances of a situation or environment that discourages/encourages development of skills, abilities and competencies
Social influences (norms)	Interpersonal processes that can cause individuals to change their thoughts, feelings or behaviours
Emotions	Complex reaction pattern, involving experiential, behavioural and physiological elements
Behavioural regulation	Anything aimed at managing or changing objectively observed or measured actions

Adapted from Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implement Sci* 2012;**7**:37.[215] This article is published under license to BioMed Central Ltd. This is an Open Access article distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/2.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

captured all issues that could affect implementation of an intervention, and that the results are grounded in the context required for this particular intervention. The three context-specific domains addressed particular questions set out in our protocol:

1. Could intervention(s) be delivered in a way that encourages access and uptake, for example be delivered in community settings or use new technologies such as digital media?
2. Can intervention(s) be delivered within existing budgets? If so, what are their associated opportunity costs and if not, would the potential cost, including training, be prohibitive?
3. Do intervention(s) provide access to more specialist services such as STI treatment and psychological support?

The potential cost of the intervention was a key issue discussed throughout the events and well captured by the 30 domains of the DTS method. It was included here to ensure that any issues specific to the commissioning arrangements of England and Scotland could be probed further. For each context, we presented the concept that was to be discussed and got the experts to discuss the barriers to, or facilitators of, implementing the intervention in relation to this. *Table 19* illustrates the contexts and our framing questions.

Data collection and analysis

Individual response sheets were completed for each domain by the group facilitator, noting down the key barriers/facilitators and/or bullet points on how the intervention might need to change mentioned by the group. Response sheets were collated and reviewed by a single researcher. Responses from each group were tabulated by domain and content analysis was used to record the key recurrent issues in the *Results*. Data from the Glasgow and London events were compared and consolidated and used to prepare a narrative summary of the key barriers and facilitators identified by the experts. Similarities and differences by domain were mapped to create a synergistic matrix of the key elements that would need to be addressed in optimisation of the candidate intervention prior to manualisation and a Phase II feasibility study. The matrix of results is presented as a Venn diagram.[216]

Results

Session 1: systemic barriers and facilitators

In session 1 we asked participants to consider the systemic barriers to, or facilitators of, using the 16 domains of NPT. Here we report on the key changes that participants suggested would be required to allow implementation in the settings in which they currently work. Findings are reported across the four NPT constructs (coherence, cognitive participation, collective action and reflexive monitoring) described in *Table 17*.

TABLE 19 Contextual barriers to, and facilitators of, implementation

Contexts	Definition	Framing questions
Cost	Commissioning, resources, existing budgets	Is it likely that the intervention can be delivered via current commissioning arrangements?
		Is it likely that the intervention can be delivered within existing budgets?
		Would potential costs, including training, be prohibitive?
Community settings	Non-NHS sites, community organisations, outreach	Is it likely that the intervention can be delivered in community settings?
		How could the intervention provide access to specialist services, such as STI treatment, psychological support?
New technologies	Online, digital media, social media	Is it likely that the intervention could be delivered online via social media or social networking sites?

Coherence (domains 1–4)

Understanding what the intervention is

Experts were asked to consider if the intervention could be distinguished from their current ways of working, if they felt they could agree on its purpose and understand what would be required of them to deliver it and if they could see the value of it.

Although participants were able to make sense of the candidate intervention and see how it would be operationalised, there were also a number of issues that they thought would have to be addressed in order for it to be implementable. Some relate specifically to how the intervention will be presented and described to the staff and organisations involved, while others present more fundamental issues about the content and framing of the intervention (*Table 20*).

There was generally thought to be a need to provide greater justification for the intervention, in terms of both the evidence informing the intervention and its potential value to organisations involved (i.e. in cost savings and the acquiring of transferable skills that could be used elsewhere by staff). The content of the intervention would also need to be more clearly defined, particularly in terms of what the visual aid, or graphic novel, would entail. The outcomes in terms of what the intervention is aiming to change, how this will be measured and what it will involve for staff would also need to be clearly specified. Although such aspects would be fully laid out in future trial materials, the experts suggested that these are required to

TABLE 20 Key systemic barriers to, or facilitators of, intervention implementation

Domain	Key systemic barriers to, or facilitators of, implementation	Areas of change suggested by expert groups
Coherence		
Differentiation	Possible time constraints to delivering intervention	Branding
Communal specification	Name of intervention could be a barrier	Length of intervention
Individual specification	Difficult to triage clients into intervention	Screening: need to clarify who is eligible/need to
Internalisation	Outcomes, including measurement, are not clear	Justify why only this group
	Content/use of the visual aid is not clear	Justification for intervention
	Intervention could be more holistic	Content of intervention needs to be clearly defined
	Staff might not engage with intervention	Process beyond intervention and what it involves for staff needs to be clear
	Justification for the risk profile/targeting required	Outcomes: what the intervention aims to change needs to be clear
	Justification of the evidence base is required	
	Transferability to non-HIV-related issues is of value	
	Proof of efficacy is required to demonstrate value to commissioners	
Cognitive participation		
Initiation	Key staff to support the intervention could differ by organisation	Stakeholder consultation
Enrolment	Piloting required to convince local opinion leaders/ staff of value	Intervention delivery
Legitimation	Uptake will depend on context, that is location and population of clinics	Justification for intervention

TABLE 20 Key systemic barriers to, or facilitators of, intervention implementation (*continued*)

Domain	Key systemic barriers to, or facilitators of, implementation	Areas of change suggested by expert groups
Activation	Link to national organisations/networks to gain support	Resources
	Proof of efficacy required	Content of intervention and trial needs to be clearly defined
	Staff might be willing to support the intervention, but lack of resources will prevent this	Trial support
	Intervention materials need to be of high standard	Training
	Demonstrate opportunity costs	
	'Buy-in' will depend on workload	
	Staff will require protected time for delivery and supervision	
	Need to identify the most appropriate staff to deliver the intervention	
	Continual assessment/feedback mechanism required to keep staff engaged in delivery	
Collective action		
Interactional workability	Delivery of intervention needs to be integrated into staff roles	Intervention delivery
Relational integration	Need to assess core skills/competence of staff before training	Training
Skill set workability	Staff might require pre-training in MI	Intervention fidelity
Contextual integration	Training refreshers and appraisals will be required	Resources
	Training and delivery could be limited to a core group, for example health advisors	Justification of intervention
	Flexibility might be required in when the intervention is delivered and by whom	Intervention content
	Supervision and follow-up training will be required	
	Cost of attending training could be an issue	
	Lack of structural support could be a barrier	
Reflexive monitoring		
Systematisation	Process of dissemination/updates required to maintain staff engagement	Trial delivery
Communal appraisal	Managers/commissioners will require output data to support intervention	Intervention delivery
Individual appraisal	Collect anonymous feedback from staff that can then be shared to maintain support	Evaluation
Reconfiguration	Use group supervision to share experience and feedback	Intervention fidelity
	Use practitioner logs for in time evaluation	Justification of intervention
	Ensure adequate buy-in to original development and training so that change is not required during delivery	
	Feedback needs to be restricted and collected at set times	

help support understanding of the purpose of the intervention and to demonstrate its value. A further element that required clarification related to who would be eligible to receive the intervention. Finally, there was concern about the delivery of the intervention immediately following the HIV-negative test result. This would present a barrier because of the way negative results are currently given to people, that is, not face to face. Having to change work processes in order to deliver the intervention could be impractical in many clinical settings.

A particular issue requiring attention is how the intervention is branded and there was concern that the 'How to stay HIV negative' tagline could alienate potential participants and stigmatise others (e.g. those living with HIV). Basing the branding of an intervention on identity instead of behaviour was questioned and it is clear that this approach would require further testing with potential users, and gay men in particular, prior to assessing the feasibility of the intervention.

Cognitive participation (domains 5–9)

Understanding who in an organisation would have to be involved, how they will be enrolled, engage with and support the work

Experts were asked to what extent they thought that key individuals would drive the intervention forward, and whether or not they would support and engage with it, both at initiation and over time.

Participants at the expert events were broadly supportive of the intervention, but there were a number of issues raised in how best to get staff enrolled in, and engaged with, it (see *Table 20*). Again, it was suggested that further justification of the evidence for the intervention would be required for this purpose, as would a clear definition and description of the content of the intervention, and also the trial designed to test it, within any training manual provided. This would need to include a clear description of the practicalities of delivering the intervention.

It was suggested that further focused stakeholder consultation would be required to identify the key individuals that would support the trial of the intervention and that getting these on board would require the detailed justification of the intervention (i.e. of why this particular intervention is expected to reduce risk-related behaviour) and of its content. It was suggested that evidence and piloting of the material utilised and the visual aid would be required for this purpose. In addition, engagement was suggested to centre on trial support.

There were also concerns that resource constraints would limit engagement with the intervention. This would include which staff should deliver it and there were competing views on this. Some suggested all staff should be trained to deliver the intervention, whereas others thought that although others could recruit and triage, the delivery of the intervention itself should be limited to health advisors or staff trained in delivering health advisory roles. The candidate intervention model presented to the experts suggested that 2 days' training would be required and some of the experts suggested that this would need to be reinforced with 'top-up' training during the course of the intervention. Feedback, continual assessment and updates on effectiveness were all thought to be key elements of ensuring ongoing engagement with the intervention.

Collective action (domains 9–12)

Understanding how the actions of those involved will promote or inhibit the intervention from working

Experts were asked if they thought staff could perform the tasks required by the intervention, would support each other in delivery and whether or not it would be supported and appropriately allocated at the organisational level.

In terms of the work required to deliver the intervention, training was suggested to be a key issue (see *Table 20*). The experts suggested that training refreshers and appraisals (possibly via e-learning)

would be required beyond the initial training sessions. It was also suggested that intervention delivery would need to be integrated into staff roles to give recognition for the work involved and to ensure that it happened. The groups suggested that staff would require basic competency in the skills related to the intervention and that these should be assessed before training, but there was disagreement whether or not staff delivering the intervention required prior MI training. There was also disagreement whether intervention delivery should be limited to health advisors or offered out to other staff (peer educators were suggested as another alternative). Beyond training, it was suggested that supervision of those delivering the intervention would be key to ensuring fidelity (as would an ongoing measure of competency).

Although less prominent, there was still a recognised need to use justification for the intervention to support the work that would be required to deliver it, particularly in terms of justifying the resources required. For example, the experts suggested that there might need to be flexible in when the intervention is delivered and by whom, so the manual would need to clearly justify the rationale for these aspects of the intervention to ensure fidelity. Resource decisions were further affected by the intervention content; for example, it was suggested that reducing the length of the intervention might reduce pressure on existing resources (time, staff and financial). This was deemed to be particularly important in gaining institutional support.

Reflexive monitoring (domains 13–16)

Understanding impact via formal and informal appraisal of the intervention

Experts were asked about the importance to staff of being able to access information about the effects of the intervention, assess effectiveness and modify working as a result.

The experts were keen that appraisal methods were incorporated into delivery of the trial, citing the need to seek and collect feedback from staff providing the intervention while it is being delivered (see *Table 20*). It was suggested that regular updates on the impact of the intervention and comparing it with the effects of other programmes elsewhere would encourage intervention delivery and continue to engage practitioners. It was even suggested that checking effectiveness could be an intervention task, that is in recalling participants to the clinic to review progress. Various methods of evaluation were suggested, including a live tool, practitioner log and recording of intervention sessions. In addition to providing feedback, these would enable measurement of intervention fidelity and it was also suggested that group supervision could be used for this purpose, and at the same time delivering informal feedback to the staff involved.

However, it was also recognised that it would not be possible or appropriate to change the intervention as a result of the feedback from providers and instead it was suggested that feedback was sought and used in the initial development of the intervention and that we ensure there is adequate buy-in to the original development of intervention materials and training so there is no need to change these during the trial. For this reason, feedback should be restricted and given at particular times and presented to intervention providers as process evaluation to inform future development of the intervention beyond the trial. This highlights that a feasibility trial would need to assess the acceptability of intensive intervention fidelity monitoring.

Session 2: psychosocial barriers and facilitators

Session 2 asked participants to consider the psychosocial barriers to, or facilitators of, staff in their organisations implementing the intervention using the 16 domains of the TDF. Here we report on the key barriers and facilitators, which would need to be addressed to optimise the intervention. This will inform the content of the intervention manual and the training provided to those delivering the intervention.

Knowledge

Some of the experts were concerned about the level of knowledge that would be required of staff in delivering the intervention, given that more than just understanding the intervention would be required (*Table 21*). It was suggested that training would need to cover HIV literacy, MSM, behaviour change, self-efficacy and cultural context.

TABLE 21 Key psychosocial barriers to, and facilitators of, intervention implementation

Domain	Key psychosocial barriers	Key psychosocial facilitators
Knowledge	• Staff require knowledge on HIV literacy, MSM, behaviour change, self-efficacy and cultural context to deliver the intervention	• Knowledge can be provided through training
Skills	• Heterogeneity of current staff skill mix • Not all staff use MI • MI training does not provide the full range of skills required for intervention	• Staff unconsciously competent: doing it already, without naming it • Referral to highly skilled staff possible • Widespread training in MI • Easy to 'up-skill' if trained in MI
Professional roles/identity	• Some staff see testing as a clinical role and behaviour change as a different responsibility • Different staff have different skill sets • Clinicians will not want to deliver the intervention, not in their skill set • Challenge to get staff to focus on intervention given all other programmes they have to implement	• Some staff already accustomed to delivering behavioural interventions • Within remit of health promotion role and psychological/MI skill set of sexual health advisors • Compatible with professional standards and identity • Credible intervention of measurable value
Beliefs about capabilities	• Staff in mainstream sexual health services may not be as confident in working with MSM • Staff may not feel capable of identifying men who meet the inclusion criteria • Staff may not feel confident in challenging risk-related behaviours (more used to dealing with the consequences) • Staff capabilities dependent on how ready patients are to change behaviour	• Staff have good supervision and regular training • Training on the structure/clarity of intervention will give staff confidence to deliver it • Ongoing support and supervision is normally provided to staff
Optimism	• Staff are sceptical about behaviour change interventions • Limited evidence base for the intervention will decrease optimism • Optimism will be dented if intervention fails	• Good cultural optimism in MI • Will be supported by understanding of the theory behind intervention • Optimism will increase if evidence supports it • Staff welcome new tools to try out
Beliefs about consequences	• Intervention will have negative impact on current services • Intervention will compare badly with biomedical interventions • 'Failure' of intervention impacts on clinicians • Intensive psychological intervention carries additional personal stresses and consequences for staff • Little opportunity to see outcomes at individual level	• Practitioners need to believe it will be more effective than current interventions that they are delivering • Other professionals are able to deal with repeated failure (e.g. smoking cessation) • Good supervision can address experiential aspects of delivering the intervention • Client satisfaction could be built in to a feedback mechanism
Reinforcement	• Not connected to career progression • Lack of accreditation for training • Seen as more work for little reward • Outcomes long term and intangible	• CPD incentives to participate in training • Transferable skills for use in other areas • Feedback on the usefulness/effect of the intervention from the client (most powerful) or the research team
Intentions	• Intentions restricted by lack of time and resources	• Management and organisational buy-in can support intentions

TABLE 21 Key psychosocial barriers to, and facilitators of, intervention implementation (*continued*)

Domain	Key psychosocial barriers	Key psychosocial facilitators
Motivation and goals	• Behaviour change not viewed as a goal • Prioritisation of biomedical approach • Service standards mean other approaches are more valued by the organisation and staff are motivated to deliver these • Desire to continue with the standard current intervention	• Genuine desire to help people be healthier • Being engaged in a research study and contributing to the evidence base could empower staff • Staff want to respond to patients' problems • Offering something different to client group • Strong leadership and professional peer buy-in will motivate staff • Well matched to current sexual health advisors aspirations • Permission to talk a different way about prevention (i.e. not condoms) • Novel approach will be supported
Memory and decision processes	• Might not be clear on where/when to deliver the intervention in the current staff/clinic structure • Reliant on individual staff remembering to deliver the intervention • May forget to deliver intervention when faced with competing demands to do tests, deal with other health issues, etc.	• Questions to determine inclusion are routine in practice • Decision-making assisted by inclusion criteria • Use of prompts/reminders for staff to follow in delivering the intervention • Require easy access to prompts/resources to keep refreshed
Environmental context and resources	• Medical model of health in clinics does not focus on prevention • Lack of space, time and staff resources • Unpredictable staff workloads • Systems in place for consultations could limit ability to deliver intervention • Clients do not expect to be in clinic for time required for intervention • Home sampling and testing may limit clients coming in for testing	• Clinics are well set up for this type of intervention • Protect time to deliver intervention • Clear limits on what is required of staff • Use waiting list for intervention • Use a self-screening or pre-triage tool to save time • Booked appointments for high-risk men, factoring in the time required for the intervention • Change to point-of-care testing to get test result during consultation
Social influences (norms)	• Lack of organisational support for intervention • NHS culture of being asked to do more with less • Different professional backgrounds could be dismissive of the intervention • Competing peer views of priorities • View that MSM should not be the priority • Focus on one group is counter to current culture to be inclusive and ensure equality of access	• Leadership/policy support for the intervention • Existing culture of change in sexual health clinics • Peer support for delivery of interventions, including shadowing/observing others • Provision of client stories of going through interventions to influence health-care professional delivery • Develop similar interventions for other groups
Emotions	• Clinical delivery tends to be removed from emotion • Staff concern about evoking a lot of emotion in clients • Staff seek to avoid emotionally charged situations if lack of supervision/guidance in dealing with these • Staff anxiety in delivering new skills	• Growing permission to feel and deal with emotion • Appropriate support/supervision of staff to deal with emotional responses • Promote insight into emotional response
Behavioural regulation	• Fear of completing a tick-box exercise	• Integration to existing patient pathway • Audit

CPD, continuing professional development.

Skills

The heterogeneity of current staff skills was envisaged to be a barrier, although some thought that staff could be doing much of the work of the intervention without necessarily realising it (see *Table 21*). MI skills and techniques were discussed as a barrier and facilitator, in that not all staff use MI and in itself MI did not cover all of the required skills of delivering the intervention. On the other hand, widespread training in MI was seen to be a facilitator, as was the ease with which those already trained in this could be up-skilled to deliver the intervention. An alternative suggestion was for intervention delivery to be limited to highly skilled staff.

Professional roles/identity

Delivery of behaviour change interventions was seen as an area of challenge and not considered to be the responsibility of everyone in a clinical setting (see *Table 21*). This may reflect differences in service design; in some services health advisors are individuals with a very clearly defined role in prevention, whereas in others health advisor skills are embedded in a larger number of individuals with multiple roles within the clinical team. Although competing priorities were also seen to be a barrier, the intervention was considered credible and compatible with professional standards.

Beliefs about capabilities

The experts thought that staff in mainstream sexual health services may not be as confident working with MSM as those in specialist services, while all might not feel capable of identifying men eligible for the intervention and/or challenging their risk-related behaviours (see *Table 21*). Clear training followed by good supervision and ongoing support were seen as the means of addressing these issues. An issue without an immediately obvious facilitator was that staff capabilities would be dependent on how ready patients are to change behaviour; however, clearly this could also be addressed in the training for intervention providers.

Optimism

The experts thought that some staff might be sceptical about behaviour change interventions in general, and of this intervention in particular, given its limited evidence base (see *Table 21*). Conversely, there was thought to be some cultural optimism in MI and support for the intervention could be supported by developing staff understanding of the theory behind it. Although optimism was thought to be at risk if the intervention was seen to fail, there was a belief that staff would welcome the opportunity to try out the new tool.

Beliefs about consequences

There was a concern that the intervention would have a negative impact on current services and compare badly with potential biomedical interventions (see *Table 21*). Its failure could potentially impact on clinicians and involve additional personal stress. However, other professional groups were thought able to deal with repeated failure (e.g. smoking cessation), which could be learned from. It was also suggested that good supervision could counter negative beliefs. One issue affecting consideration of consequences was that there is often little opportunity to see outcomes at the individual level in interventions, and a facilitator to mediate this could be the use of client satisfaction measurements.

Reinforcement

The experts were concerned that delivering the intervention would not be connected to career progression and without accreditation, and it would risk being seen as more work for little reward (see *Table 21*). Highlighting the transferable skills that would be obtained was suggested as one possibility, as was seeking continuing professional development incentives for the training. Feedback was considered to be an important element of reinforcement, particularly when the outcomes are long term and relatively intangible.

Intentions

Few barriers and facilitators were identified for intentions, largely because of considerable overlap with other domains (see *Table 21*). However, it was suggested that intentions could be restricted by lack of time and resources. Seeking strong management and organisational support would counter this.

Motivations and goals

A key barrier was that behaviour change would not be seen as a goal by all staff or would lose out to the prioritisation of a biomedical approach (see *Table 21*). However, the experts thought that staff had a genuine desire to help people and respond to their problems and that being involved in a research study would empower them to do so, as would offering something different to the client group. It was suggested that the novel approach (and an alternative to a sole focus on condom use) would be valued and fit particularly well with particular groups' aspirations (such as health advisors), but it would require strong leadership and professional peer buy-in to support it.

Memory and decision processes

Current clinic/staff structures could present a barrier to the intervention in that it might not be clear where and when to deliver it (see *Table 21*). However, the inclusion criteria were considered to aid decision-making and the questions that these would require were seen to be routine in current practice. There was concern that the intervention would be reliant on individual staff remembering to deliver it, particularly when faced with competing demands on their time, but the use of prompts and reminders could easily facilitate this.

Environmental context and resources

Although clinics were thought to be well set up to deliver this type of intervention, there was also concern that the medical model limited focus on prevention (see *Table 21*). The experts agreed that lack of space, time and staff resources were real barriers to implementation, and protecting staff time as well as looking at novel means by which to deliver some of the intervention components were suggested as facilitators. Clients' expectations of having short appointments presented another barrier to an intervention envisaged to take 30–50 minutes to complete. Barriers were also presented in terms of expected changes with regard to testing technology, in as much as self-sampling and testing for the presence of HIV may reduce client visits to clinics and opportunity for intervention delivery. Future-proofing the ways behaviour change interventions should dovetail with technological innovations was important.

Social influences

The lack of organisational support was considered to be a key potential barrier to the intervention, and strong leadership and policy support would be vital (see *Table 21*). Despite concern over increasing pressure to deliver more for less, the expert group did think the culture of change in sexual health services could be a facilitator to behaviour change. Organisational support would also need to be matched by peer support for the delivery of interventions, particularly to counter competing peer views of priorities. There was also concern that the intervention's focus on one particular group of MSM could run counter to the current culture of inclusivity and equality and, as such, it may be necessary to consider how the intervention could be adapted for other groups in the future.

Emotions

Few barriers and facilitators were identified in relation to emotions, although there was some concern about evoking negative emotions in clients and that staff might seek to avoid 'emotionally charged' situations (see *Table 21*). Appropriate support and guidance would be required to alleviate these concerns.

Behavioural regulation

There were also few barriers and facilitators identified in relation to behavioural regulation, although, again, there was overlap with other domains (see *Table 21*). To avoid the intervention becoming a 'tick-box exercise', the expert groups suggested it could be integrated into existing patient pathways and subject to audit.

Session 3: contextual barriers and facilitators

Finally, to ensure that the DTS analysis was grounded in the context required for this particular intervention, participants were asked to discuss the potential impact of the three contextual issues on delivery of the intervention: cost, settings and new technologies.

Cost

There was real concern that this intervention would be seen as too expensive (*Table 22*). Experts across both Scotland and England suggested that there was limited capacity in existing, tight, budgets, particularly in terms of ongoing or repeated delivery. Some thought existing services could absorb the costs and/or the work could be embedded within existing staff (in this case, health advisors) roles and that the intervention would need to be seen as another tool in the existing prevention toolbox.

Settings

We asked the experts to consider if the intervention could be delivered in community settings and there was support for an 'off the peg' intervention being delivered by varied organisations, for third-sector involvement and for the NHS to provide the intervention in community settings (see *Table 22*). However, there were concerns that staff in some organisations might not have the skills or competencies required to deliver the intervention or the governance frameworks required to support it. On the other hand, it was thought that some organisations would have the necessary frameworks in place and an enthusiastic, trained workforce, which could deliver the intervention in a less restricted environment.

New technologies

Finally, we asked the experts if they thought that the intervention could be delivered online via social media or social networking sites (see *Table 22*). Although digital media were recognised to be useful for geographically remote access and elements of the intervention could be facilitated through apps, Skype™ (Microsoft Corporation, Redmond, WA, USA), or online links, there were concerns about security issues,

TABLE 22 Key contextual barriers to, and facilitators of, intervention implementation

Domain	Key contextual barriers	Key contextual facilitators
Costs	• Limited capacity within existing services • Existing budgets very tight, and ongoing costs would be difficult to meet • Requirement for more staff if third sector not involved in delivery • Intervention would be seen as expensive • Training costs could be too expensive • Delivery of the intervention not likely to be continued or repeated	• Some services could absorb the costs • Could embed in existing health advisor role • Could work alongside PrEP, as an alternative option • Present potential reductions in cost of treatment if diagnoses reduced • See intervention as another tool in the prevention toolbox
Settings	• Some NHS boards do not fund third sector, so could not provide in community settings • Depending on organisations, staff may not have the skills/competence required to deliver intervention • Governance frameworks less well developed in community organisations • Might have limited slots in which to deliver the intervention • Might have to prioritise it over other options (e.g. condom delivery) • Would have to refer into specialist services for other STI testing and trauma support	• Off the peg intervention could be provided by varied organisations • Third sector could be used to reach populations not using NHS specialist clinics • NHS could provide in community settings • Community organisations may already have framework and trained workforce in place • Less restricted environment • Enthusiasm will be there
Technologies	• Security of technology could be a problem in the NHS • Technology becomes out dated quickly • May lose personalisation of the intervention • Limited evidence of effectiveness for delivery of the intervention via online methods • Online would change the intervention completely	• Digital media is good for remote access • Graphic novel could be delivered via an app • Could book an appointment through an app or online link • Could prepare for intervention with video, banners, game, etc. • Face-to-face consultations via Skype™ (Microsoft Corporation, Redmond, WA, USA) • Could have additional aspect that is online (i.e. risk reduction app) • Online might be useful to link to self-testing

technology becoming outdated and the loss of the personalised aspects of the intervention facilitated by face-to-face contact. The expert groups also thought that there was limited evidence of the effectiveness of delivery via online methods and that moving to this would change the intervention completely.

Dual theoretical synergy matrix of key barriers to, and facilitators of, intervention implementation

Having identified the major systemic and psychosocial barriers to, and facilitators of, intervention implementation through the NPT and TDF sessions, respectively, and the contextual factors specific to this intervention in particular, the final stage of the DTS analysis combined the results to assess how the individual (i.e. psychosocial) issues are embedded in the systemic and contextual. Similarities and differences by domain were mapped to create a DTS matrix. *Figure 10* is a visual representation of the matrix and shows the overlap in the systemic, psychosocial and contextual issues that need to be addressed in optimisation of the intervention. This process identifies the elements of the intervention that will have to be refined and operationalised prior to feasibility testing in order to take forward a candidate intervention that is likely to be implementable in the future.

Key recurrent issues that were evident across all three levels were resources, training, and staff roles. Issues that crossed the systemic and psychosocial levels were institutional support, completing priorities, patient eligibility, intervention delivery, intervention length, feedback and supervision/appraisal processes. Staff competency was identified as an issue at the systemic level (in both the primary clinical setting and

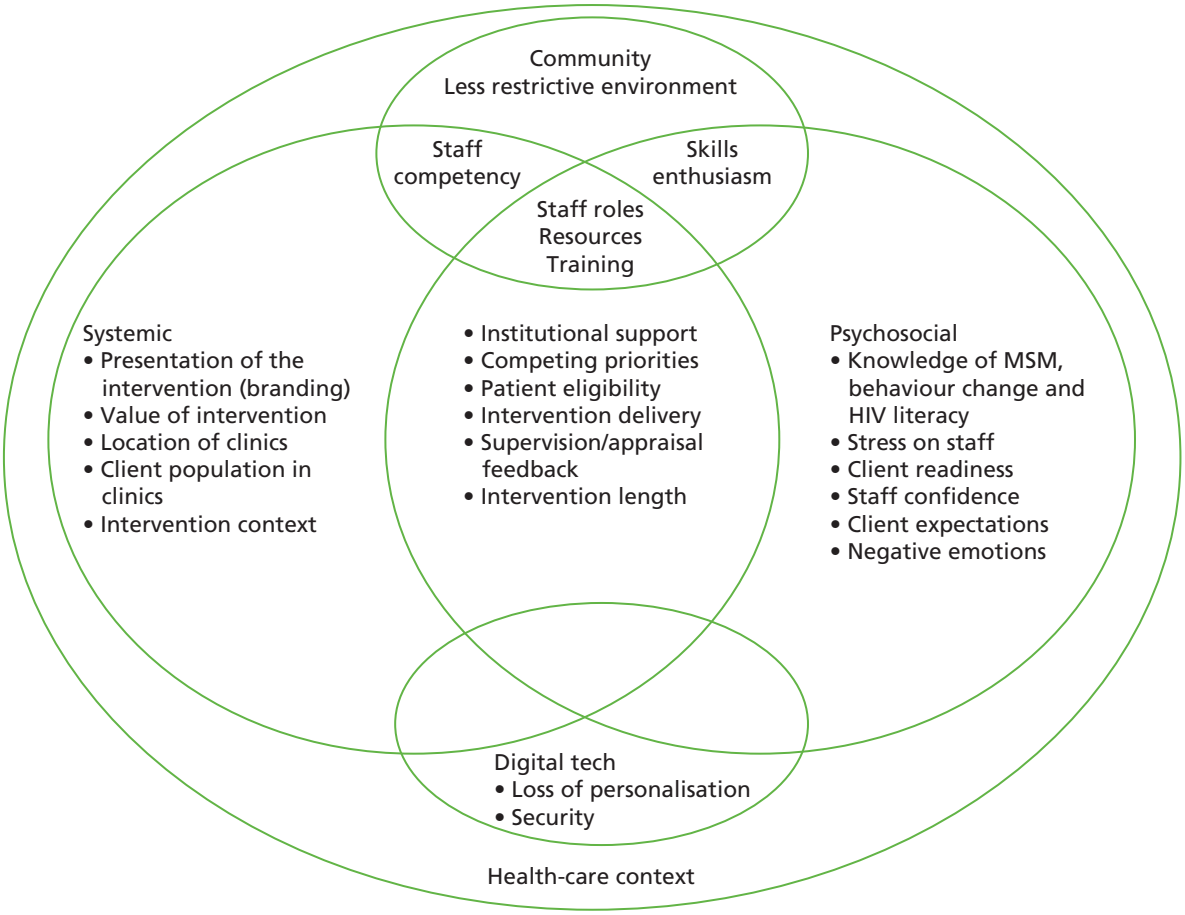

FIGURE 10 Dual theoretical synergy matrix of systemic, psychosocial and contextual issues to be addressed in optimisation of the 'How to stay HIV negative' intervention.

community settings), whereas staff skills and enthusiasm (presence or absence) were identified as potential issues at the psychosocial and community levels. Further key issues at the systemic level were the presentation of the intervention (branding), location of clinics and client population in clinics. Further issues at the psychosocial level were knowledge, stress on staff, staff confidence, client readiness, client expectations and negative emotions. Finally, at the contextual level, security and loss of personalisation were suggested issues for delivering the intervention via digital technology, and the less restrictive environment was suggested as a potential facilitator in the community settings. In summary, these issues demonstrate that optimisation of the intervention requires focus on institutional support, intervention delivery, intervention content and training.

Gaining institutional support, at all levels within organisations, will be key to future testing of the intervention, and there was generally thought to be a need to provide greater justification for the intervention, both in terms of the evidence informing the intervention and its potential value (i.e. in terms of transferable skills) to organisations involved. Although there was a belief that staff would be enthusiastic and welcome the opportunity to try out a new tool, there would be a need for further stakeholder consultation to identify the key individuals (commissioners and practitioners) that would be required to support any trial. Requests for more evidence and piloting demonstrate the importance of linking between the current evidence generated by the systematic review and the need to explain why the candidate intervention should be evaluated before being rolled out in practice. The limited evidence base for the candidate intervention suggests a pilot evaluation might first be required. Resources, or rather lack thereof, was a key issue throughout the expert events, and was deemed to be particularly important in gaining institutional support.

There were concerns that resource constraints would limit engagement with the intervention and careful thought will need to be given to intervention delivery, in terms of where it is provided and by whom, as a result. Who should deliver the intervention generated competing views and this merits further attention, although health advisors were identified as one of the staff groups likely to already have many of the skills required. This does have resource implications, and peer educators and/or outsourcing to the third sector were suggested as alternatives. Alternative means of delivery could be explored and were recognised to be useful for geographically remote access. Delivery in community settings (by third-sector organisations and/or the NHS) was thought to be a possibility and a less restricted environment, but the same issues about the capabilities of staff to deliver the intervention would apply. Additional concerns about security issues, technology becoming outdated and the loss of the personalised aspects of the intervention if delivered through apps, Skype™ or online links may limit their potential. There was further concern about the delivery of the intervention immediately following a HIV-negative test result. In practice, most people are not given this result face to face and any such change to clinical structures and work practices would have significant resource implications.

The content of the intervention would also need to be more clearly defined, particularly in terms of what the visual aid or graphic novel would entail. This is required, first, to help support understanding of the purpose of the intervention and to construct the value of it (key elements of whether or not someone would be willing to support and implement the intervention) and, second, to ensure that staff can be fully trained in its delivery (to facilitate intervention fidelity). A particular issue raised by some of the experts was the intervention's branding and the acceptability of the 'How to stay HIV negative' tagline. Branding would be one aspect to explore in further consultation with potential users, and gay men in particular, prior to assessing the feasibility of the intervention. Content could also be affected by resource decisions. The suggested length of the intervention (30–50 minutes) was deemed to present too much pressure on existing resources (time, staff and financial).

Training was suggested to be a key issue. The intervention would be reliant on individual staff remembering to deliver it and feeling capable in identifying and recruiting eligible men when faced with competing demands of their time. Accreditation, prompts/reminders, training refreshers and appraisals (possibly via e-learning) were additionally suggested. Beyond training, it was suggested that supervision, continual assessment, feedback and updates (and an ongoing measure of competency) of, and for,

those delivering the intervention would be key to ensuring fidelity and ongoing engagement with the intervention.

It was suggested that training would be required in terms of HIV literacy, MSM, behaviour change, self-efficacy and cultural context, in addition to intervention content and delivery, to ensure that staff had the skills required to deliver the intervention. Work is also required to address how the nuances of contemporary risk management strategies (i.e. the impact of other biomedical HIV infection prevention such as PrEP on these) would affect the screening and identification of potential clients for the intervention. The grounding of the intervention in MI skills and techniques was discussed as a barrier to, and facilitator of, behaviour change, but widespread training in this was seen to be a facilitator, particularly as those trained already could easily be up-skilled to deliver the intervention. This is clearly dependent on who delivers the intervention and the varied capabilities of different staff groups would have to be addressed in the training, as would concerns with delivering particular aspects of the intervention, for example challenging risk-related behaviours, addressing the extent to which clients were ready to change behaviour and dealing with 'emotionally charged' situations. Such an intensive, psychological intervention was feared to involve additional personal stresses and consequences for staff involved; however, the experiences of other professional groups facing similar challenges could be learned from and incorporated into training.

Conclusions

To address the complexity and challenges of transferring knowledge to an increasing range of settings and intervention delivery modalities, the expert events were designed to simultaneously identify issues to be addressed in intervention manualisation and enable the optimisation of the intervention prior to feasibility testing. The DTS method identified the major systemic and psychosocial barriers to, and facilitators of, intervention implementation and the benefit of the method is in the assessment of how the individual (i.e. psychosocial) issues are embedded in the systemic and contextual (of this particular intervention). This synergistic consideration of what might facilitate or impede the intervention highlights the central elements of the intervention that will have to be refined and operationalised prior to feasibility testing.

The DTS analysis highlights that gaining institutional support and clearly defining and refining the intervention content and delivery model will be key to optimisation. In turn, extensive training will be required to ensure intervention fidelity. We have demonstrated the intervention's fit with existing service provision in the UK, including that provided by the NHS, private providers and other sectors such as voluntary organisations, including acceptability by staff and across varied geographical areas (e.g. urban and rural settings). We explored if the intervention could be delivered in a way that encourages access and uptake, for example in community settings or uses new technologies (such as digital media). None was immediately ruled out, but each presented their own challenges to operationalising the intervention. The clinical setting, with access to more specialist services such as STI treatment and psychological support if required, was deemed most appropriate. Cost and resourcing were recurrent issues and there was concern that the intervention would not be able to be delivered within existing budgets. It was clear that the health economics of the intervention would have to be included as part of its evaluation. In the light of concern that such behaviour change interventions would not be prioritised over biomedical prevention, such as post-exposure prophylaxis after sexual exposure and PrEP, it will be important to demonstrate how the two can complement each other in the future, as will evaluating the fit of the intervention if testing service delivery models change because of greater use of self-sampling and testing for HIV.

Most importantly, none of the experts thought that the candidate intervention would be impossible to implement or evaluate. Instead, the DTS method has highlighted how the intervention can be best optimised in order to take forward a candidate intervention that is most likely to be implementable in the future.

Chapter 7 Conclusions

Main findings

Overall, the trials included in this review ($n = 10$) reported positive findings and suggest that individual-level behavioural change interventions are effective in reducing HIV risk-related behaviour in HIV-negative MSM. Overall, there was a statistically significant reduction in the risk of UAI (risk ratio 0.75, 95% CI 0.62 to 0.91). However, there is much clinical and statistical heterogeneity among these studies. As a result, this pooled estimate must be interpreted with caution.

With regard to intervention content, when removing BCTs shared with controls, the most common groups of BCTs used within interventions related to 'goals and planning', 'identity', 'social support' and 'comparison of outcome'. In terms of individual BCTs the most commonly used were 'pros and cons', 'goal-setting', 'social support (emotional)', 'framing and reframing' and 'incompatible beliefs'. All interventions were based on theory to some extent, although there was considerable variation in the type and numbers of theories utilised. There was some evidence of the use of theory-congruent BCTs.

Exploratory stratified meta-analyses suggest that face-to-face delivery of interventions may be more effective than interventions delivered via telephone or online, that interventions delivered immediately after testing may be associated with greater treatment effects, that interventions containing BCTs from the 'goals and planning' and 'identity' groups may potentially be more effective than those with more heterogeneous and less common BCT components and, potentially, that interventions that have more theory-congruent BCTs may be more effective than those that contain fewer theory-congruent BCTs. Again, these results must be interpreted with caution.

To illuminate review findings further, and provide direction for intervention development, a post hoc realist review was conducted. It suggested the explication of behaviour, to both quantify and mentally re-enact sexual risk, is an important step in client's recognising their risky sexual behaviour. Furthermore, it suggested that interventions can be enhanced by supportive, skilled facilitation. Skilled interventionists can create educationally sensitive moments that balance the clients vulnerability with insights into their potential to change behaviour and patterns of associated thought. Clients should be supported in the development of plans and goals. The realist review also suggested that opportunities to rehearse planned behaviours and thinking styles are likely to enhance the intervention. Throughout interventions, the reduction of negative, internalised emotions such as shame is likely to be central to the exploration and future planning of new skills and behaviours. These findings are the result of a sustained and interpretative activity and, again, are limited by the small number of trials included, the subjective nature of this approach (conducted by a single reviewer) and the inferred causality that structures this approach.

In order to develop a more detailed candidate intervention, an additional analysis of the review data was conducted. This focused on an attempt to assess intervention content as a whole rather than in terms of its individual components. It examined patterns and trends within intervention content addressing the number, order and relative purpose of intervention components. This suggested that most of these effective interventions comprised multiple components, delivered with increasing complexity and often focusing on a single developmental or narrative trajectory. Interventions were marked by the first intervention component being different than subsequent components. Moreover, the majority of interventions began with a personal assessment of risk, often conducted with little initial interaction with the interventionist. This assessment of personal risk usually included exposure to relative risks faced by peers. Similarly, the majority of interventions ended with a component that focused on the future, often with the client setting goals or agreeing an action plan. The majority of interventions were personalised and tailored to clients' individual needs, and most also had a distinct focus on intrasubjective elements

with the aim of getting clients to take responsibility for their behaviour change and to identify potential ways to achieve it. The majority of interventions could also be seen to demonstrate cultural competency with respect to the sexual environments and the concomitant dilemmas faced by MSM at the time of their implementation. Once more the results of this supplemental analysis should be treated with caution. They too rely on a single reviewer and a novel methodological approach.

Finally, the review details issues of transferability and overall acceptability regarding the candidate intervention developed within this review. Multidisciplinary experts ($n = 24$), including MSM ($n = 9$), agreed that the intervention was possible to implement and evaluate. They highlighted key ways that the candidate intervention could be optimised.

Wider considerations for evidence synthesis regarding behaviour change

Beyond the primary goal of addressing the project's aims and objectives, the team identified additional issues that may be useful for other researchers conducting similar projects to reflect on and discuss. These relate to considering the scope and implications of search strategies with regard to choices of outcome measures in relation to their locus and specificity, inclusive approaches to mapping the content of interventions and the relative role of theory within utilising BCT taxonomies. We discuss each of these issues in turn.

A behavioural focus for outcome measures

In developing search strategies for evidence syntheses regarding behaviour change interventions, the relative importance, or hierarchy, of outcome variables utilised may differ from those employed within efficacy and effectiveness studies. Considering both the locus, and specificity, of outcome variables is important to yield the most useful knowledge with regard to understanding behaviour change. With regard to locus of outcome variables, those that relate to behaviour change per se are arguably more important and indeed more useful than outcomes that relate to the consequences of behaviour (reflecting a much more complex causal chain). This is true across a range of health conditions. For example, not everyone who smokes will die of lung cancer and useful knowledge relating to smoking cessation per se offers insights into behaviour change and forms a good locus for cumulative knowledge. However, a behavioural locus of outcomes for developing cumulative knowledge for behaviour change is perhaps particularly important within infectious disease when infection also relates to factors outwith the control of the individual. Population-level issues, such as incidence, prevalence and the density of social networks associated with transmission, impact on exposure to a disease sometimes irrespective of individual actions. So depending on the epidemiological context, people engaging in the same risk-related behaviours may have very different chances of being exposed to a disease. For the current study, for example, if we had developed only cumulative behavioural knowledge from outcome data relating to reduced HIV transmission (affecting only a very small fraction of those people who failed to change their behaviour), sample sizes within primary studies would have had to have been far larger and we would have lost valuable data relating to factors associated with behaviour change across the larger population (i.e. those who did not change their behaviour, but were not exposed to HIV). Therefore, HIV transmission data as primary outcome data reflect exposure (a combination of population incidence and prevalence and patterns of sexual mixing) in addition to the role of behaviour change. Therefore, in this context, it may be useful to prioritise behaviour change outcomes for behaviour change evidence syntheses rather focusing on the consequences of behaviour change.

Similarly, it is important to consider the specificity of outcome measures employed within evidence synthesis concerning behaviour change interventions. It is assumed that if studies do not provide data regarding a behavioural locus but do address consequential outcomes of behaviour change, the latter must

be directly and indisputably related to the behavioural domain that interventions are manipulating. Problems may arise, however, when consequential outcomes are infrequent (e.g. the example of HIV transmission), and researchers may be tempted to use more frequent, highly correlated proxy outcomes (such as bacterial STIs, which are much more common than HIV transmission). When doing so it is vital to consider the specificity of proxy measures in relation to the behavioural domain that is being manipulated through interventions. For example, the behavioural domain of HIV transmission is distinct from that of many bacterial STIs. The use of PrEP to reduce HIV transmission may actually increase STI transmission, or in more behavioural terms, adopting unprotected oral sex (low HIV transmission risk) rather than anal sex (high HIV transmission risk) to reduce HIV transmission may not change STI-related outcomes (as oral sex is associated with high STI transmission risk), but would change HIV-related outcomes (as HIV transmission through oral sex is very uncommon). In this way, it may be useful for researchers to ensure a direct congruence between the behaviours that are being changed by interventions and the outcomes that are reported, particularly if they are consequences of behaviour change rather than behaviour change itself. This modelling of outcomes may well inform decisions regarding the locus of outcomes and should be core to developing search strategies in relation to choice of outcomes.

Inclusive attempts to map intervention content

The work embodied within this report has also integrated a range of approaches to mapping intervention content; the BCT taxonomy, realist review approaches and ways of looking at the synergistic content of diverse intervention components. All of these approaches are encompassed within the broad field of implementation science yet each stems from a separate epistemological position. Each has its relative merits and weaknesses. Here we discuss our reflections on the varied approaches we adopted and discuss the ways in which they might help health researchers.

With regard to utilising the BCT taxonomy[72] to map the content of interventions, the strengths of this approach focus on its granularity (e.g. discrete, replicable and irreducible techniques) and the development of a common and highly specific language to describe particular BCTs. This perspective enables researchers to look across diverse interventions and identify commonality of intervention components irrespective of the way that original authors describe that content. In this way it can compensate for disciplinary, national, cultural or historical trends in reporting intervention content and represents a foundational moment in building cumulative knowledge for behavioural insights. This approach is grounded within a positivist epistemology and makes the most of ideas of cumulative knowledge to conduct effective implementation science. Its weaker aspects reflect its very strengths. Weaknesses include the inability to examine the effects of the context in which its granular components are delivered, for example the ways in which the ordering of BCTs may lead to amplifications (e.g. boosting each others effectiveness) and neutralisations (e.g. cancelling each other out), or indeed cumulative or additive effects (where it is the effectiveness of BCTs delivered sequentially) that makes the most effective active ingredients.

Our original goal was to develop methods to systematically identify patterns in the BCTs used in our interventions, to enable network meta-analysis[95] grouping interventions together on the basis of the patterning of BCTs in order to give novel explanatory purchase regarding effectiveness. In this way we had hoped to address the contexts of the BCTs as embedded within interventions. However, owing to the small number of studies identified within the current project, the analysis lacked the necessary statistical power. Nevertheless, this approach may well prove very fruitful for other behavioural evidence syntheses in which larger numbers of intervention studies are available. There is also scope for methodological innovation in coding patterns of BCTs across what appear to be heterogeneous interventions in order to preserve the benefits of their granularity but also address their sequential patterning. In this way analytic techniques, such as network meta-analysis, can deliver comparisons of interventions reflecting the degree of similarity of intervention content.

The second approach to mapping intervention content used within the project was realist review and synthesis.[205–210] It represents an alternative inductive epistemological approach that also delivers useful knowledge regarding the role of intervention content within particular contexts. Its iterative and explanatory focus enables knowledge generation in ways that are not constrained by a priori assumptions and that focus primarily on explanation. Strengths of the approach are to deliver a grounded explanatory theory from a given data set, rather than through the lens of an 'off the shelf' theoretical framework drawn from any given disciplinary tradition or indeed within the highly specific framework suggested by the BCT taxonomy. Realist analysis also allows for the identification of latent factors through reflexivity, interpretation and abstraction that might inform how a specific intervention works to produce specific outcomes. The realist review approach may be useful in providing a useful counterpoint to the more rigid frameworks suggested by formal theory or indeed the highly specific framework of the approaches such as the BCT taxonomy.[72] Whereas realist review and synthesis gains explanatory purchase with regard to novel perspective in relation to explaining intervention effectiveness, its weaker aspects relate to the transferability of its insights across domains. Its ability to contribute to cumulative knowledge is thus limited, but counterbalanced, by its context-bound relevance.

The final approach related to our earlier attempt to use network meta-analysis to examine the patterning of individual BCTs to examine some aspects of the intervention contexts. It focused on describing and interpreting potential synergies across descriptions of intervention components. It addressed the ways intervention content, delivery and context combined. For the current project with its focus on intervention development, this particular approach proved very useful for creating a brief mock intervention manual. It looked at normative patterns in the flow of interventions and enabled a sense of how the findings of the BCT taxonomy could be combined with insights from the realist synthesis. This approach uses inductive reasoning to describe normative patterns within intervention flow. Although it does contribute to cumulative knowledge, it does not do so with the rigour and specificity of the BCT taxonomy approach.

Theory and mapping intervention content

Across a range of disciplines the meaning and function of theory can differ dramatically. Overall, there is little conceptual coherence regarding 'theory', 'models' and 'frameworks'. At times these terms appear interchangeable and dependent on disciplinary context. Theory is probably most often understood as representing a heuristic device, or explanatory tool, that suggests or illuminates a common pattern in a given phenomenon. In this way theory can represent the way that a phenomenon works for most people, most of the time and can give useful direction for the identification of trigger points for intervention or the targeting of resources. However, in other fields theory can relate to the formal specification of a predictive model often pitched in terms of a single discipline-specific focus, for example in terms of cultural factors (sociology), structural factors such as sociodemographics (epidemiology) and cognitive or affective factors (psychology).

The epistemology of the current study is rooted within implementation science and the primacy of applied research. Throughout we have adopted a diverse range of methods reflecting our pragmatic approach. For the team an inclusive and interdisciplinary approach to theory has also been adopted within the current project: making the most of generic social scientific approaches such as realist synthesis, as well as making the most of contemporary health psychology and its increasingly practice-oriented nature. Following an almost exclusive disciplinary focus on building and refining psychological theory at the cognitive level for the last 40 years, there has been a notable trend to enhance the practical application of psychology within the health domain. This shift does not represent a rejection of the cognitive realm, or a neo-behaviourist turn, but does represent a focus on practical application. Moreover, while a trend towards increasing use of theory within behavioural interventions has been reported,[69] there is no consensus regarding whether or not the use of theory within behaviour change interventions enhances their effectiveness. Some authors have found a positive correlation between theory and effectiveness.[70–73] However, others have found that the relationship is not so clear.[74,75]

The BCT taxonomy approach to evidence synthesis is not contingent on theory: it can work independently of any theoretical framework. As such, and unlike other approaches such as intervention mapping,[217] it does not focus on theory or theoretical constructs per se. In some ways it is 'agnostic' to theory and instead, its primary focus is on the techniques themselves and for evidence synthesis how the use of techniques relates to effectiveness. However, it is worth noting that it is entirely possible to 'reverse engineer' theory from this end point and it would be entirely reasonable to expect some resonance with more formal theory.

Limitations and strengths

The review and its findings are limited by factors associated with its primary studies. Despite an inclusive operationalisation of population criteria, very few trials were found which could be included within the review. In the primary studies there was considerable methodological and statistical heterogeneity. In terms of assessing intervention content and delivery, findings are limited by an over-reliance on published papers rather than intervention manuals or detailed protocols. There was a lack of process evaluations, which would have further illuminated intervention effects and exposed potential confounding factors. Relatedly, there was limited evidence of intervention fidelity being assessed rigorously within the trials. Again, these findings highlight the need for caution when interpreting these results. Similarly, in the chapters on realist synthesis (see *Chapter 4*) and intervention elements (see *Chapter 5*), sole reviewers took the lead with data extraction and analysis and no independent analysis took place. A realist synthesis would also typically search and select studies based on more qualitative criteria (depth and richness of intervention description). However, as this was a post hoc realist synthesis, it was limited to those studies included under meta-analysis criteria and, therefore, cannot fully fulfil its potential in synthesising all available and appropriate evidence. Compensatory approaches were adopted, however, including by the reviewers' approach to including all outcomes reported in the studies, and not just those of interest to the meta-analysis (UAI).

The strengths of the review relate to both its detailed appraisal of intervention content and its innovative use and development of methodology. In relation to intervention content, for the first time within this field the review has provided detailed descriptions of the content of interventions in terms of BCTs employed. In this way it has illustrated the viability of examining evidence at this degree of granularity. In terms of methodological innovation, as a useful counterpoint to approaches that focus on the granularity of intervention content, the current review used a post hoc realist synthesis. This approach offered perspectives regarding potential factors that may be associated with increased effectiveness which were not limited by a priori assumptions and beliefs. Similarly, an approach to assessing intervention content was developed which charted the episodic and sequential components of the interventions. Finally, at the experts' events, which focused on issues of potential implementation, a DTS was developed which integrated insights from existing approaches used within implementation science. Although these innovations have yielded new and useful knowledge, their findings should again be interpreted with caution given their novelty.

Assessment of factors relevant to the NHS and other parties

No UK-based evidence exists which details the effectiveness of one-to-one brief behavioural interventions among MSM. Expert events demonstrated considerable demand and enthusiasm for such evidence. Expert events demonstrated the candidate intervention's fit with existing service provision in the UK, including that provided by the NHS, private providers and other sectors such as voluntary organisations, including acceptability by staff and across varied geographical areas (e.g. urban and rural settings). Intervention delivery was explored and experts concluded that the candidate intervention could be delivered in a way that encourages access and uptake, for example in community settings or using new technologies such as digital media. No settings were immediately ruled out, but each presented challenges to operationalising the intervention. The clinical setting, with access to more specialist services such as STI treatment and psychological support if required, was deemed most appropriate. Cost and resourcing were recurrent

issues and there was concern that the intervention would not be able to be delivered within existing budgets. It was clear that the health economics of the intervention would have to be included as part of its evaluation. In the light of concern that such behaviour change interventions would not be prioritised over biomedical prevention, such as post-exposure prophylaxis after sexual exposure and PrEP, it will be important to demonstrate how the two can complement each other in the future, as will evaluating the fit of the intervention if testing service delivery models change because of greater use of self-sampling and testing for HIV. Findings from the expert events highlighted a number of issues that would enhance the acceptability and feasibility of such interventions. They highlighted the importance of institutional support and clearly defined and refined intervention content and details of delivery. Experts also noted that extensive training would be required to ensure intervention fidelity.

Implications for service provision

Despite the limited evidence base and potential concerns about the transferability of knowledge, the current review does suggest the effectiveness of one-to-one, brief behavioural interventions for MSM who are HIV negative. Moreover, it provides clear direction to how best to develop and deliver such interventions. For example, exploratory stratified meta-analyses suggested face-to-face delivery of interventions may be more effective than interventions delivered via telephone or online, and those delivered immediately after testing may be associated with greater treatment effects. With regard to intervention content, the most commonly used BCTs were identified and the BCT groups from which interventions should be drawn were identified. Similarly, we concluded that an intervention should deliver a demonstrable sense of cultural competency, be multicomponent and be composed of sequential elements; it should begin with a risk assessment exercise, include a normative peer reference point and the use of discrete tools, and end with a future-facing element.

These findings and many others are directly applicable to intervention design. However, the breadth and detail of the conclusions of the meta-analysis and review findings and the expert event, and the heterogeneity of the studies analysed, mean that the direct application of the findings to clinical practice at this stage is unlikely to be possible. The use of the findings to develop a candidate intervention for use in a further clinical trial or trials, as suggested in our recommendations, would be the means of realising the benefits of this research in clinical practice. Evaluation of a candidate intervention should necessarily include operational outcomes (such as time taken, location and how it would fit within existing HIV infection testing clinical pathways, for example when many HIV infection test results are no longer delivered face to face) in addition to staff factors (training required, incentives for engagement and retention in the use of the intervention, measuring competencies to deliver it) and subsequent financial factors, operating within a budget-constrained setting. Opportunity costs will also need to be evaluated. The move, in England, of commissioning to local authorities with a specific public health mandate may foster support for more preventative interventions such as this. Many of these topics were raised during the expert events (see *Chapter 6*), and should inform both the candidate intervention and its evaluation.

Suggested research priorities

UK-based RCTs of brief one-to-one behaviour change interventions among HIV-negative MSM who are at high risk should be conducted. Such trials should be accompanied by comprehensive process and economic evaluations.

Prior to such trials, a comprehensive package of further intervention development work could encompass (in sequential order):

1. Further intervention development work:
   Primarily qualitative implementation research focusing on intervention development is needed to specify the content, and duration, of interventionist training, and the ways to address the barriers and facilitators specified within this report (approaches such as the 'behaviour change wheel') may be appropriate.
   Mixed-methods research focusing on intervention development is needed to ensure that brief individual behaviour change interventions are complementary to biomedical interventions such as PrEP.
   Primarily qualitative research focusing on intervention development is needed to ensure that brief individual behaviour change interventions can be offered within the diversity of settings and across the range of HIV infection testing technologies available.
   Experimental quantitative and complementary qualitative research focusing on intervention development is needed to validate the proposed mechanisms of behaviour change suggested by the candidate intervention.
2. The acceptability and feasibility of individual behaviour change interventions:
   Primarily qualitative methods research addressing the acceptability and feasibility of brief individual behaviour change interventions among MSM across diverse national and local settings is needed.
3. Trials of individual behaviour change interventions:
   Following a demonstration of the acceptability and feasibility of an individual behaviour change intervention that builds on the work described here, multisite trials across a range of regions in the UK should be conducted.
   Interventions must be well-designed with particular attention paid to intervention content, theoretical base and mode of delivery. Intervention content should be reflected within intervention manuals that detail the episodic sequential elements of their composition in addition to details regarding BCTs employed. Such trials must be well-designed, appropriately powered with particular attention paid to issues of retention and attrition.
   Mixed-methods process evaluations should be conducted to illuminate a range of issues including intervention fidelity, the role of confounders, mechanisms of action and issues concerned with local implementation.
   There is a need for modelling and behavioural economics studies to determine the relationship between behaviour change effect sizes and likely public health impact across a range of outcome measures.
4. Additional methodological work:
   Finally, mixed-methods research focusing on methodological development is needed regarding ways of assessing the sequence and potential synergistic and cumulative effects of intervention components.

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Data sharing statement

Data can be obtained from the corresponding author.

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Appendix 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses checklist

Title		Recommendation	
Title	1	Identify the report as a systematic review, meta-analysis or both	i
Abstract			
Structured summary	2	Provide a structured summary including, as applicable, a background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; and systematic review registration number	xxiii
Introduction			
Rationale	3	Describe the rationale for the review in the context of what is already known	18–20
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes and study design (PICOS)	23–24
Methods			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g. web address) and, if available, provide registration information including registration number	
Eligibility criteria	6	Specify study characteristics (e.g. PICOS, length of follow-up) and report characteristics (e.g. years considered, language, publication status) used as criteria for eligibility, giving rationale	24–25
Information sources	7	Describe all information sources (e.g. databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched	24
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated	139–141
Study selection	9	State the process for selecting studies (i.e. screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis)	25
Data collection process	10	Describe method of data extraction from reports (e.g. piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators	25
Data items	11	List and define all variables for that data were sought (e.g. PICOS, funding sources) and any assumptions and simplifications made	
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis	25
Summary measures	13	State the principal summary measures (e.g. risk ratio, difference in means)	25–27
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g. I^2) for each meta-analysis	
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g. publication bias, selective reporting within studies)	25
Additional analyses	16	Describe methods of additional analyses (e.g. sensitivity or subgroup analyses, metaregression), if done, indicating which were prespecified	

Results		Recommendation	
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram	29
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g. study size, PICOS, follow-up period) and provide the citations	29
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome-level assessment (see item 12)	52–53
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group; and (b) effect estimates and CIs, ideally with a forest plot	31–36
Synthesis of results	21	Present the main results of the review. If meta-analyses are done, include for each CIs and measures of consistency	30, 37, 41, 42, 45, 52, 53, 56, 58–64
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see item 15)	52
Additional analysis	23	Give results of additional analyses, if done [e.g. sensitivity or subgroup analyses, metaregression (see item 16)]	
Discussion			
Summary of evidence	24	Summarise the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g. health-care providers, users and policy-makers)	111
Limitations	25	Discuss limitations at study and outcome level (e.g. risk of bias), and at review level (e.g. incomplete retrieval of identified research, reporting bias)	115
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research	111–117
Funding			
Funding	27	Describe sources of funding for the systematic review and other support (e.g. supply of data); and role of funders for the systematic review	viii

PICOS, participants, interventions, comparisons, outcomes and study design.

Appendix 2 Literature search strategies: MEDLINE example

Database searched: MEDLINE.

Platform or provider used: ProQuest.

Date of coverage: 2000 to September 2014.

Search undertaken: 15 September 2014.

	Term	Number of identified studies
1	MESH.EXACT("Sexually Transmitted Diseases")	20,221
2	(MESH.EXACT("HIV Infections") OR MESH.EXACT("HIV")) OR MESH.EXACT("Acquired Immunodeficiency Syndrome") OR MESH.EXACT("HIV Seronegativity")	208,453
3	MESH.EXACT("Sexually Transmitted Diseases") OR ((MESH.EXACT("HIV Infections") OR MESH.EXACT("HIV")) OR MESH.EXACT("Acquired Immunodeficiency Syndrome") OR MESH.EXACT("HIV Seronegativity"))	223,229
4	(HIV-negative OR hiv negative) OR (seronegativ* OR hiv uninfect* OR hiv NEAR negativ*) OR (hiv NEXT test*)	49,787
5	(MESH.EXACT("Sexually Transmitted Diseases") OR ((MESH.EXACT("HIV Infections") OR MESH.EXACT("HIV")) OR MESH.EXACT("Acquired Immunodeficiency Syndrome") OR MESH.EXACT("HIV Seronegativity")) OR (MESH.EXACT("Sexually Transmitted Diseases") OR ((MESH.EXACT("HIV Infections") OR MESH.EXACT("HIV")) OR MESH.EXACT ("Acquired Immunodeficiency Syndrome") OR MESH.EXACT("HIV Seronegativity")))) AND ((HIV-negative OR hiv negative) OR (seronegativ* OR hiv uninfect* OR hiv NEAR negativ*) OR (hiv NEXT test*))	20,311
6	(MESH.EXACT.EXPLODE("Preventive Health Services:N.02.421.143.827") OR MESH.EXACT.EXPLODE("Preventive Health Services:N.02.421.726")) OR (MESH.EXACT.EXPLODE("Intervention Studies:N.05.715.360.775.390") OR MESH.EXACT.EXPLODE("Intervention Studies:E.05.318.760.565") OR MESH.EXACT.EXPLODE("Intervention Studies:N.06.850.520.450.565"))	428,665
7	(prevent* OR intervention*) OR (method* OR trial* OR study* OR evaluat* OR educat* OR teach* OR motivat* OR counsel* OR interview*)	13,652,975
8	(((MESH.EXACT.EXPLODE("Preventive Health Services:N.02.421.143.827") OR MESH.EXACT.EXPLODE("Preventive Health Services:N.02.421.726")) OR (MESH.EXACT.EXPLODE("Intervention Studies:N.05.715.360.775.390") OR MESH.EXACT.EXPLODE("Intervention Studies:E.05.318.760.565") OR MESH.EXACT.EXPLODE("Intervention Studies:N.06.850.520.450.565"))) OR ((prevent* OR intervention*) OR (method* OR trial* OR study* OR evaluat* OR educat* OR teach* OR motivat* OR counsel* OR interview*))) AND ((MESH.EXACT("Sexually Transmitted Diseases") OR ((MESH.EXACT("HIV Infections") OR MESH.EXACT("HIV")) OR MESH.EXACT("Acquired Immunodeficiency Syndrome") OR MESH.EXACT("HIV Seronegativity")) OR (MESH.EXACT("Sexually Transmitted Diseases") OR ((MESH.EXACT ("HIV Infections") OR MESH.EXACT("HIV")) OR MESH.EXACT("Acquired Immunodeficiency Syndrome") OR MESH.EXACT("HIV Seronegativity")))) AND ((HIV-negative OR hiv negative) OR (seronegativ* OR hiv uninfect* OR hiv NEAR negativ*) OR (hiv NEXT test*)))	16,790
9	(MESH.EXACT("Behavior") OR MESH.EXACT("Behavior Therapy")) OR MESH.EXACT ("Sexual Behavior") OR MESH.EXACT("Social Behavior") OR MESH.EXACT("Health Behavior")	153,259
10	MESH.EXACT("Risk-Taking") OR MESH.EXACT("Risk Reduction Behavior") OR MESH.EXACT("Safe Sex") OR MESH.EXACT("Unsafe Sex")	28,816

	Term	Number of identified studies
11	(risk NEXT behavio*) OR (risk NEXT sexual OR behavio* NEXT sexual)	2629
12	((MESH.EXACT("Behavior") OR MESH.EXACT("Behavior Therapy")) OR MESH.EXACT ("Sexual Behavior") OR MESH.EXACT("Social Behavior") OR MESH.EXACT("Health Behavior")) OR (MESH.EXACT("Risk-Taking") OR MESH.EXACT("Risk Reduction Behavior") OR MESH.EXACT("Safe Sex") OR MESH.EXACT("Unsafe Sex")) OR ((risk NEXT behavio*) OR (risk NEXT sexual OR behavio* NEXT sexual))	174,497
13	((((MESH.EXACT.EXPLODE("Preventive Health Services:N.02.421.143.827") OR MESH.EXACT.EXPLODE("Preventive Health Services:N.02.421.726")) OR (MESH.EXACT.EXPLODE("Intervention Studies:N.05.715.360.775.390") OR MESH.EXACT.EXPLODE("Intervention Studies:E.05.318.760.565") OR MESH.EXACT.EXPLODE("Intervention Studies:N.06.850.520.450.565"))) OR ((prevent* OR intervention*) OR (method* OR trial* OR study* OR evaluat* OR educat* OR teach* OR motivat* OR counsel* OR interview*))) AND ((MESH.EXACT("Sexually Transmitted Diseases") OR ((MESH.EXACT("HIV Infections") OR MESH.EXACT("HIV")) OR MESH.EXACT("Acquired Immunodeficiency Syndrome") OR MESH.EXACT("HIV Seronegativity")) OR (MESH.EXACT("Sexually Transmitted Diseases") OR ((MESH.EXACT ("HIV Infections") OR MESH.EXACT("HIV")) OR MESH.EXACT("Acquired Immunodeficiency Syndrome") OR MESH.EXACT("HIV Seronegativity")))) AND ((HIV-negative OR hiv negative) OR (seronegativ* OR hiv uninfect* OR hiv NEAR negativ*) OR (hiv NEXT test*)))) AND (((MESH.EXACT("Behavior") OR MESH.EXACT("Behavior Therapy")) OR MESH.EXACT("Sexual Behavior") OR MESH.EXACT("Social Behavior") OR MESH.EXACT("Health Behavior")) OR (MESH.EXACT("Risk-Taking") OR MESH.EXACT ("Risk Reduction Behavior") OR MESH.EXACT("Safe Sex") OR MESH.EXACT("Unsafe Sex")) OR ((risk NEXT behavio*) OR (risk NEXT sexual OR behavio* NEXT sexual)))	2005
14	(MESH.EXACT("Homosexuality") OR MESH.EXACT("Homosexuality, Male")) OR MESH.EXACT("Sexuality") OR MESH.EXACT("Bisexuality") OR (MESH.EXACT ("Transgendered Persons") OR MESH.EXACT("Transsexualism"))	28,094
15	(men who have sex with men) OR (MSM OR gay) OR (bisexual* OR homosexual*) OR transsexual*	54,879
16	((MESH.EXACT("Homosexuality") OR MESH.EXACT("Homosexuality, Male")) OR MESH.EXACT("Sexuality") OR MESH.EXACT("Bisexuality") OR (MESH.EXACT ("Transgendered Persons") OR MESH.EXACT("Transsexualism"))) OR ((men who have sex with men) OR (MSM OR gay) OR (bisexual* OR homosexual*) OR transsexual*)	59,151
17	(((((MESH.EXACT.EXPLODE("Preventive Health Services:N.02.421.143.827") OR MESH.EXACT.EXPLODE("Preventive Health Services:N.02.421.726")) OR (MESH.EXACT.EXPLODE("Intervention Studies:N.05.715.360.775.390") OR MESH.EXACT.EXPLODE("Intervention Studies:E.05.318.760.565") OR MESH.EXACT.EXPLODE("Intervention Studies:N.06.850.520.450.565"))) OR ((prevent* OR intervention*) OR (method* OR trial* OR study* OR evaluat* OR educat* OR teach* OR motivat* OR counsel* OR interview*))) AND ((MESH.EXACT ("Sexually Transmitted Diseases") OR ((MESH.EXACT("HIV Infections") OR MESH.EXACT ("HIV")) OR MESH.EXACT("Acquired Immunodeficiency Syndrome") OR MESH.EXACT ("HIV Seronegativity")) OR (MESH.EXACT("Sexually Transmitted Diseases") OR ((MESH.EXACT("HIV Infections") OR MESH.EXACT("HIV")) OR MESH.EXACT("Acquired Immunodeficiency Syndrome") OR MESH.EXACT("HIV Seronegativity")))) AND ((HIV-negative OR hiv negative) OR (seronegativ* OR hiv uninfect* OR hiv NEAR negativ*) OR (hiv NEXT test*)))) AND (((MESH.EXACT("Behavior") OR MESH.EXACT("Behavior Therapy")) OR MESH.EXACT("Sexual Behavior") OR MESH.EXACT("Social Behavior") OR MESH.EXACT("Health Behavior")) OR (MESH.EXACT("Risk-Taking") OR MESH.EXACT ("Risk Reduction Behavior") OR MESH.EXACT("Safe Sex") OR MESH.EXACT("Unsafe Sex")) OR ((risk NEXT behavio*) OR (risk NEXT sexual OR behavio* NEXT sexual)))) AND (((MESH.EXACT("Homosexuality") OR MESH.EXACT("Homosexuality, Male")) OR MESH.EXACT("Sexuality") OR MESH.EXACT("Bisexuality") OR (MESH.EXACT ("Transgendered Persons") OR MESH.EXACT("Transsexualism"))) OR ((men who have sex with men) OR (MSM OR gay) OR (bisexual* OR homosexual*) OR transsexual*))	778

	Term	Number of identified studies
18	(((((MESH.EXACT.EXPLODE("Preventive Health Services:N.02.421.143.827") OR MESH.EXACT.EXPLODE("Preventive Health Services:N.02.421.726")) OR (MESH.EXACT.EXPLODE("Intervention Studies:N.05.715.360.775.390") OR MESH.EXACT.EXPLODE("Intervention Studies:E.05.318.760.565") OR MESH.EXACT.EXPLODE("Intervention Studies:N.06.850.520.450.565"))) OR ((prevent* OR intervention*) OR (method* OR trial* OR study* OR evaluat* OR educat* OR teach* OR motivat* OR counsel* OR interview*))) AND ((MESH.EXACT ("Sexually Transmitted Diseases") OR ((MESH.EXACT("HIV Infections") OR MESH.EXACT ("HIV")) OR MESH.EXACT("Acquired Immunodeficiency Syndrome") OR MESH.EXACT ("HIV Seronegativity")) OR (MESH.EXACT("Sexually Transmitted Diseases") OR ((MESH.EXACT("HIV Infections") OR MESH.EXACT("HIV")) OR MESH.EXACT("Acquired Immunodeficiency Syndrome") OR MESH.EXACT("HIV Seronegativity")))) AND ((HIV-negative OR hiv negative) OR (seronegativ* OR hiv uninfect* OR hiv NEAR/4 negativ*) OR (hiv NEXT test*)))) AND (((MESH.EXACT("Behavior") OR MESH.EXACT("Behavior Therapy")) OR MESH.EXACT("Sexual Behavior") OR MESH.EXACT("Social Behavior") OR MESH.EXACT("Health Behavior")) OR (MESH.EXACT("Risk-Taking") OR MESH.EXACT ("Risk Reduction Behavior") OR MESH.EXACT("Safe Sex") OR MESH.EXACT("Unsafe Sex")) OR ((risk NEXT behavio*) OR (risk NEXT sexual OR behavio* NEXT sexual)))) AND (((MESH.EXACT("Homosexuality") OR MESH.EXACT("Homosexuality, Male")) OR MESH.EXACT("Sexuality") OR MESH.EXACT("Bisexuality") OR (MESH.EXACT ("Transgendered Persons") OR MESH.EXACT("Transsexualism"))) OR ((men who have sex with men) OR (MSM OR gay) OR (bisexual* OR homosexual*) OR transsexual*)) Limits applied	514
19	(((((MESH.EXACT.EXPLODE("Preventive Health Services:N.02.421.143.827") OR MESH.EXACT.EXPLODE("Preventive Health Services:N.02.421.726")) OR (MESH.EXACT.EXPLODE("Intervention Studies:N.05.715.360.775.390") OR MESH.EXACT.EXPLODE("Intervention Studies:E.05.318.760.565") OR MESH.EXACT.EXPLODE("Intervention Studies:N.06.850.520.450.565"))) OR ((prevent* OR intervention*) OR (method* OR trial* OR study* OR evaluat* OR educat* OR teach* OR motivat* OR counsel* OR interview*))) AND ((MESH.EXACT("Sexually Transmitted Diseases") OR ((MESH.EXACT("HIV Infections") OR MESH.EXACT("HIV")) OR MESH.EXACT("Acquired Immunodeficiency Syndrome") OR MESH.EXACT("HIV Seronegativity")) OR (MESH.EXACT("Sexually Transmitted Diseases") OR ((MESH.EXACT ("HIV Infections") OR MESH.EXACT("HIV")) OR MESH.EXACT("Acquired Immunodeficiency Syndrome") OR MESH.EXACT("HIV Seronegativity")))) AND ((HIV-negative OR hiv negative) OR (seronegativ* OR hiv uninfect* OR hiv NEAR/4 negativ*) OR (hiv NEXT test*)))) AND (((MESH.EXACT("Behavior") OR MESH.EXACT("Behavior Therapy")) OR MESH.EXACT("Sexual Behavior") OR MESH.EXACT("Social Behavior") OR MESH.EXACT("Health Behavior")) OR (MESH.EXACT("Risk-Taking") OR MESH.EXACT ("Risk Reduction Behavior") OR MESH.EXACT("Safe Sex") OR MESH.EXACT("Unsafe Sex")) OR ((risk NEXT behavio*) OR (risk NEXT sexual OR behavio* NEXT sexual)))) AND (((MESH.EXACT("Homosexuality") OR MESH.EXACT("Homosexuality, Male")) OR MESH.EXACT("Sexuality") OR MESH.EXACT("Bisexuality") OR (MESH.EXACT ("Transgendered Persons") OR MESH.EXACT("Transsexualism"))) OR ((men who have sex with men) OR (MSM OR gay) OR (bisexual* OR homosexual*) OR transsexual*)) Limits applied	508

Appendix 3 Excluded studies with rationale

Not a randomised controlled trial/behavioural randomised controlled trial

Chesney MA, Koblin BA, Barresi PJ, Husnik MJ, Celum CL, Colfax G, *et al.* An individually tailored intervention for HIV prevention: baseline data from the EXPLORE study. *Am J Public Health* 2003;**93**:933–8.

Bowen A, Williams M, Daniel C, Clayton S. Internet based HIV prevention research targeting rural MSM: feasibility, acceptability, and preliminary efficacy. *J Behav Med* 2008;**31**:463–77.

Bull SS, Lloyd L, Rietmeijer C, McFarlane M. Recruitment and retention of an online sample for an HIV prevention intervention targeting men who have sex with men: the Smart Sex Quest Project. *AIDS Care* 2004;**16**:931–43.

Carrico AW, Flentje A, Gruber VA, Woods WJ, Discepola MV, Dilworth SE, *et al.* Community-based harm reduction substance abuse treatment with methamphetamine-using men who have sex with men. *J Urban Health* 2014;**91**:555–67.

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Appendix 4 Summary of context, mechanisms and outcomes extracted

Authors (year of publication)	Contexts	Mechanisms	Outcomes
Picciano *et al.* (2007)[106]	Serostatus	Respect?	Monogamy
	Negotiated sexual positions	Questionnaire tailors intervention	Increase adjustment in more readiness to change for primary partners
	'Safer' relationships	Quantification of risk with feedback	Decreased number of partners
	Self-assessment questionnaire	Mobilise own change resources	Decreased frequency of UAI, especially with non-primary partners
	MI	Crystallise alternatives	Increased engagement in prevention
	Feedback on personal behaviour	'Take stock'	
	Alternative change options	Translate behaviours into risks	
	Empathy		
	Goal-setting		
	Intervention not linked to test		
Carpenter *et al.* (2010)[96]	Detailed assessment and reflecting about assessment	Confront with evidence of own behaviour/awareness	Decreased unprotected sex acts over time
	Readiness for change	Motivation to change	Accurate(?) identification of partners of serostatus
	Decision balance exercises	Redefinition of previously perceived safe behaviours	Decreased sex with risky partners
	Discussion of negotiated safety	Individual paid lots of attention	Increased self-efficacy and self-value
	Intervention is very complex and time intensive	Identifies perceived barriers through critical thinking	
	Personalised feedback	Increased confidence to discuss risk unknown partners	
Christensen *et al.* (2013)[97]	Virtual decisions linked to consequences in life	Increased awareness of risk	Shame reduction
	'Gaming' format	Suggestive of possible reward (?) and age sensitive?	Reduced frequency of UAI
	Perceptions of 'wrong' behaviours judgement by others	Changing self-standards (and changing beliefs about others' beliefs)	Identification of aspects which are controllable and those which are not/less so, increases self-efficacy
	Eliciting information via questionnaire	Increased shame	
	Accepting desires as normal	Evaluate 'acceptable' behaviours to continue with and risk-related behaviours to cease or replace or change	

Authors (year of publication)	Contexts	Mechanisms	Outcomes
	Intervention is brief (30 minutes)	Reverse internalisation to be 'sex positive': sharing and openness	
	Confrontation with risk-related behaviour	Immersion and stimulation in highly charged situation that client can control	
	Ethnically customised (matched?) characters	Interruption of automatic risky choices	
	Positive self-appraisals demonstrated by avatar	Challenges choices with persuasive messages	
		Acknowledges and accepts emotions and desires	
		Creating similar identities with characters enriches affect towards them	
		Practice of initiating conversations about safe sex	
Hao *et al.* (2012)[103]	Motivation to change	Openness and engagement	Motivation to use condoms more consistently
	Voluntary	Perceived behavioural control	UAI reduced with any partner
	Structured, brief intervention	Positive attitude towards service provision(?), demonstrable commitment from service	UAI reduced with regular partners
	Cue to action bracelet (generosity)	Prompt and association	Awareness of personal risk of behaviours
	Video narration of HIV-positive same-ethnicity man sharing personal accounts	Accountability (to self and others)	
	Counsellor asks questions regarding stage of change	Critical reflection and mental conflicts	
	Discussion of pros and cons	Ownership	
	Action plan		
Parsons *et al.* (2014)[105]	Men of colour	Client receives interest, empathy	Reduced club drug use
	Therapists trained on intervention specifically	High specificity of intervention (does this reduce its efficacy for some clients?/more appropriate to some sample profiles than others?) – sensitivity and specificity considerations	Reduced risk of UAI with causal partners
	Ongoing feedback and supervision of therapists	Low on readiness to change	Increased motivation and personal responsibility
	Intervention targeting non-treatment seeking men (ambivalent to change)	Addresses wider risk issues related to sex (acting as confounders or moderators)	Increased goals for reducing both target behaviours
	Therapy linked to substance use/high-risk behaviours	Explication, ownership and internalisation of intentions	
	Focused feedback on target behaviours and comparisons with current ones	Increased self-efficacy	

Authors (year of publication)	Contexts	Mechanisms	Outcomes
	Goal-setting and action planning	Engaging material delivered by a third party removes perceptions of judgement from person-person, face-to-face interaction	
	Video segments with factual information in conjunction with structured discussion points	Optimise reflection time OR low sustain of effects, opening opportunities for risk between sessions	
	Four sessions over 12 weeks		
Coffin *et al.* (2014)[98]	Sex with substance use (dual target behaviours)	Possible confusion regarding target behaviours?	Reduced UAI with the three most recent non-primary partners in non-dependent substance users
	Personalised cognitive counselling (assumes knowledge of risks but acts in spite of it)	Increased awareness of self-talk and re-evaluation in neutral circumstances	
	Identification of self-justifications through assessment using a survey-style instrument	Identification of assumptions regarding partners' HIV status	
	Following identification of self-justifications, client explores strategies to avoid high-risk situations	Reframing self-justifications to clarify the reality of risk	
	Men of colour	Awareness of how self-justifications function in decision-making	
		Reappraise level of risk	
		Generate alternative self-statements	
Hirshfield *et al.* (2012)[104]	Baseline assessments (three surveys)	Reflection	Cost-effectiveness
	Videos: dramatisation through a neutral medium)	Critical thinking (through comparison between self and character)	Increased HIV disclosure
	Intervention not linked to test	Provocation of emotional response which dislodges usual thinking	Increased HIV infection testing (?)
	Educationally sensitive moment (recognition that something is 'not right' but not linked to the vulnerability feeling of test result)	Evoke participatory responses through discussion	Increased condom use
	No monetary incentives		Decreased substance use related to sex
	No staff training described		

Authors (year of publication)	Contexts	Mechanisms	Outcomes
Eaton *et al.* (2011)[102]	Men of colour	Judgement abilities about enquiry of HIV status	Fewer sexual partners
	Increased awareness	Exploited vulnerability	Increased enquiry regarding HIV status with partners
	Teaching moment	Re-identification of self, profiling skills	Critical thinking regarding condom use and partner selection
	Graphic representation of network	Ownership and empowerment	Increase awareness
	Cocreation of tailored plan		Condom use self-efficacy
			Probing about partner's sex history
Dilley *et al.* (2002)[101]	Self-justification (allowability of high-risk behaviours having rationalised the risk through self-talk)	Opening up to increase perceptions of personal responsibility and control	Reappraisal of risk
	Drawing contrasts and distinctions between 'online' (heat of the moment) and 'offline'	Increased self-regulation	Reduction in unknown or discordant HIV status partners by three episodes in previous 90 days
	Capabilities to critique	'Critical' examination through recall of online moment to reframe internal talk	
	Repeat testers/risk takers	Motivation to change? OR normalisation of risk?	
	Pre-assessment regarding self-justifications	Reflection on reasonability of self-justifications now. Mental preparation for verbal walkthrough of event, identify and retained information for recall in the future	
	Mental health professionals involved in interventions design and delivery	Consider causation between personal decisions (suggestive of increased control over sexual conduct) and risk	
	Diary completion	Time lag between pre-assessment and counselling allows increased absorption of self-schemas?	
	Professionals trained in intervention with supervision and feedback	Use of appropriate techniques, experienced in facilitating judgement-free conversations, ensuring personal relevance, high specificity of intervention	
	Description of sexual events in full (creation of psychological safety and low shame environment)	Walkthrough increases recall at appropriate moments in the future and the associated discomfort with confrontation/ vulnerability of risk-related behaviour	

Authors (year of publication)	Contexts	Mechanisms	Outcomes
Dilley *et al.* (2007)[100]	Identification of self-justifications	Re-evaluation of the 'cold light of day': critical reflection of judgements made	Satisfaction with care
	Recently trained professionals	High specificity in execution of intervention (highly personalised)	Swift reduction in number of episodes of UAI
	Longer consultation	Increased awareness and ownership, increased recall (proximity to fresh memories) opportunities in the future and associated discomfort regarding confrontation of extremities of behaviour	Attrition (high-risk takers left usual care arm): follow-up and prioritisation of health
	Narration, recounting of event, confronting behaviours in detail	Fear?	Sustained change
	Educationally sensitive moment as multiple testers	Evolved critical thinking skills, capacity to learn	
	Advanced degrees	Motivation to change. Paranoia?	
	Test fatigue (?): high-risk takers	Normalisation/acceptance of behaviour could increase risk	
	Repeated counselling in usual care		

Appendix 5 Mock manual: 'How to stay HIV negative'

Background

The intervention is based on an evidence synthesis of trials that all focus on brief, individual, behaviour change interventions delivered in a range of settings ($n = 11$, 10 trials). The systematic review showed that these interventions overall had small medium-term effects, although some were significant when compared with their controls. Some of these interventions have shaped prevention policy within the USA. There have been no UK trials of these kinds of interventions.

The 'How to stay HIV negative' intervention is delivered in all sites that offer HIV infection testing. It is delivered within a single session lasting between 30 and 50 minutes. It is not an intervention for the 'worried well' or for those with multiple and complex needs. It should be thought of as one of a suite of interventions available to clients. 'How to stay HIV negative' is only offered to MSM who meet all of the following criteria:

1. are seeking or accept an offer of HIV infection testing
2. have received a HIV-negative test result
3. report condom-less sex with two or more partners of HIV-positive or HIV-unknown status within the last year
4. feel ready to change their risk-related behaviour.

Goal

The goal is to reduce client behaviours that can result in the onwards transmission of HIV.

How it works

'How to stay HIV negative' works through focused multistage exploration of HIV risk and its personal significance within a single session delivered by a trained individual provider and comprises five components:

1. It examines contemporary HIV risk through the use of a peer-oriented visual aid such as a short graphic novel (which describes the role of emotions and feelings, serosorting, barebacking, PrEP, TASP, recreational drug and alcohol use in contemporary HIV risk). This has four aims: to enable a general discussion about the range of risks that MSM must manage through using a peer referent; to enable the client to feel confident in subsequently disclosing a broad range of personal information about their own behaviour; to provide information and increase HIV literacy; and, finally, it also demonstrates the cultural competency of the intervention and the practitioner.
2. It focuses on eliciting the clients most memorable risk event and explores their perceptions of its determinants. It brings to the client's mind the complexity of the challenges associated with risk and the role of feelings, thoughts and social context in shaping behaviour. The intervention skills have to be translated into real, often complex, sexual contexts, hence it encourages the client to focus on the detail of their risk event in order to build skills that can be transferred to the next risky situation.
3. The practitioner encourages the client to explore the similarities and differences between their own risk-related behaviour, and that depicted within the graphic novel. Here, the client considers the specific determinants of their behaviour, potential consequences of their actions and their susceptibility to HIV infection.
4. It assesses, and then builds further, motivation to change behaviour through encouraging the client to both formulate ways they could have done things differently and to focus on the pros and cons of these alternative behaviours. The client rehearses how they plan to do things differently in the future, details an action plan and focuses on their HIV-negative identity. They are also encouraged to consider their identity as someone who used to take HIV risks but now embrace the identity of remaining HIV negative.

5. The client articulates and commits to their personalised action plan. This supports and encourages the client's belief in their own capabilities. In this way the client leaves the session having learned about HIV risk, having detailed what made them vulnerable in the past, having identified solutions to this problem, being motivated to change behaviour, having a clear action plan of how to reduce their vulnerability and feeling more confident in their ability to implement their behaviour change plan.

Theory behind the intervention and proposed mechanism of action

'How to stay HIV negative' is not based on a single theory and draws on a range of theoretical perspectives. Its direct theoretical antecedents include the information–motivation–behavioural skill model[199] and the health action process theory.[218] These both draw on Bandura's theory of self-efficacy[198] and the theory of planned behaviour.[200] Relevant constructs relating to each component are:

1. The role of information in terms of potentially increasing knowledge concerning risk-related behaviour and the role of descriptive norms in relation to the visual aid depicting other MSM's risk-related behaviour.
2. How motivation is assessed through the disclosure of salient attitudes, norms and attributions.
3. Uses predictors from the health belief model[61] such as 'perceived susceptibility', 'perceived benefits and barriers', and 'cues to action' (through the comparative task).
4. Motivation to change is assessed and reinforced in order to focus on the client's readiness to change and prepare them for the subsequent move from motivational to action phases.[218]
5. Utilises self-efficacy[198] via building a sense of the client's capability in reducing risk in the future and resonates with the planning and rehearsal of the self-regulatory processes required to implement action plans.[218]

Research findings

'How to stay HIV negative' is adapted from the interventions included within our systematic review. Each of these effective interventions adopted a multicomponent approach that included many of the key elements detailed in the following five points. Commonalities in these studies suggested the importance of BCTs drawn from the problem-solving group of the BCT taxonomy, and suggested action planning, pros and cons and incompatible beliefs may be of particular use.

Core elements

Core elements are the essential parts of an intervention. They cannot be overlooked or modified. BCTs are listed as the irreducible active ingredients of the intervention content.

1. Peer-oriented visual aid, which details the complexity of contemporary HIV risk (emotions and feelings, serosorting, barebacking, PrEP, TASP and recreational drug and alcohol use) ('information about health consequences').
2. The provision of one-on-one counselling which focuses on the client's perceptions of the determinants of a single high-risk event ['social support (unspecified)'].
3. A client-centered appraisal of personal risk using the visual aid to compare with the high-risk event and examine client's decision-making processes ('problem-solving' and 'social comparison').
4. A practitioner- and client-focused assessment and reinforcement of motivation to change, through retrospective analysis of the ways the client could have done things differently. This is achieved by weighing up the pros and cons of alternative behaviours. The practitioner guides the client to articulate how they would do things differently in the future in order to stay HIV negative ('pros and cons', 'problem-solving', 'framing/reframing' and 'incompatible beliefs').

5. Guide the client to articulate and commit to a specific action plan, persuade them about their capability and focus them on their identity as someone who used to take HIV risks but is now 'HIV negative' ('action planning', 'identity associated with changed behaviour' and 'verbal persuasion about capability').

Key characteristics of 'How to stay HIV negative'

Conduct 'How to stay HIV negative' in the context of HIV infection testing and counselling.

Complete the intervention in one 30- to 50-minute session.

'How to stay HIV negative' can be delivered by anyone having undergone 'How to stay HIV negative' training: a 2-day intensive training course. Within this course they must demonstrate a level of competency in effective delivery.

Procedures

Screening

Potential clients must be screened for eligibility for 'How to stay HIV negative'. Clients must satisfy all criteria. The key criteria are:

1. seeking or accepting an offer of HIV infection testing
2. have received a HIV-negative test result
3. report condom-less sex with two or more partners of HIV-positive or HIV-unknown status within the last year
4. feel ready to change their risk-related behaviour.

Purposes

To determine if client is eligible for 'How to stay HIV negative' and to briefly orient (introduce) the client to the intervention. Skills required: instructing, open-ended questioning, use of neutral probes and remaining non-judgemental.

Six steps of 'How to stay HIV negative'

Step 1: the peer-oriented visual aid (e.g. graphic novel)

After the practitioner confirms eligibility, he or she asks the client to look at the visual aid.

Purposes

To normalise the complexity and range of HIV infection risk-related behaviour management issues, raise levels of HIV literacy, to demonstrate the practitioner's cultural competence with MSM.

Skills required

Instructing/directing, high levels of HIV literacy.

Resources

Peer-oriented visual aid (e.g. graphic novel).

Step 2: depth recall of high-risk incident

The practitioner helps the client recall a single high-risk event and recall how, where and why it happened.

Purposes
To personalise risk, facilitate recall of specific contexts and interactions.

Skills required
Active listening, use of open-ended questions, use of neutral probes and provision of social support with regard to risk reduction.

Step 3: risk and problem-solving
The practitioner facilitates the client's self-appraisal of risk through comparing the client's risk with recognised MSM risks as depicted within the graphic novel; the client describes their decision-making and how it led to their vulnerability.

Purposes:
To further personalise risk, identify vulnerabilities, prime for step 4.

Skills required
Active listening, use of open-ended questions, use of neutral probes, high levels of HIV literacy.

Step 4: explore alternative behaviours and reinforce motivation to change
The practitioner reflects back the client's account of decision-making and his vulnerability, asking the client to identity behavioural alternatives. The client is also asked to list reasons for wanting and/or not wanting to change; the practitioner suggests the deliberate adoption of a perspective that focuses on how to stay HIV negative as a new way of looking at risk-related behaviour and highlights how past behaviours as listed, are incompatible with this.

Purposes
To focus the client on his ability to find behavioural solutions to complex problems, to motivate the client towards behaviour change, to orient the client to an identity based on being HIV negative.

Skills required
Use of open-ended questions, identification and confidence in feeding back to clients their accounts of their vulnerability, facilitating decisional balance, facilitating client-centred behavioural alternatives, facilitating the client's HIV-negative identity.

Step 5: how things will be different
The practitioner encourages the client to articulate an action plan for the future.

Purposes
To rehearse future plans to build self-efficacy and enable the self-regulatory processes required for implementation of an action plan at further times of vulnerability.

Skills required
Instructing/directing, use of open-ended questions, use of neutral probes, and provision of social support in regards to risk reduction, building clients' self-efficacy.

Step 6: closing
'How to stay HIV negative': the practitioner summarises what the client has achieved and endorses the client's capabilities.

Differences/similarities from other interventions

Although the intervention does provide knowledge concerning the range and complexity of contemporary HIV risk management, this is not its primary concern. If clients are lacking basic HIV literacy, then they should be offered HIV literacy interventions instead of 'How to stay HIV negative'.

'How to stay HIV negative' draws on many of the central ideas of MI.

'How to stay HIV negative' is not a client-centred, or client-led, approach focusing on the client's feelings. Its focus is to proactively get clients to think about their behaviour in new ways and generate their own solutions to the problems they face.

'How to stay HIV negative' is not an approach based on reducing client short-term stress and anxiety. Practitioners may need supervision and support about their desire to contain client's short-term feelings, but these are not the focus of 'How to stay HIV negative'.

'How to stay HIV negative' is not focused on the practitioner providing the client with prepackaged easy solutions to their risk-related behaviour. It is about providing the client's self-generated insights and skills for sustainable behaviour change within complex demanding and ever changing environments.

Appendix 6 Evidence informing the candidate intervention

BOX 2 The evidence base that underpins the candidate intervention

Core elements

Core elements are the essential parts of an intervention. The core elements cannot be overlooked or modified. BCTs are listed as the irreducible active ingredients of the intervention content.

- Peer-oriented visual aid, which details the complexity of contemporary HIV infection risk (emotions and feelings, serosorting, barebacking, PrEP, TASP, recreational drug and alcohol use) ('information about health consequences'[a]).
- The provision of one-on-one counselling that focuses on the client's perceptions of the determinants of a single high-risk event ['social support (unspecified)'[b,c]].
- A client-centred appraisal of personal risk using the visual aid to compare with the high-risk event and examine the client's decision-making processes ('problem-solving',[c,d] 'social comparison'[e]).
- A practitioner- and client-focused assessment and reinforcement of motivation to change, through retrospective analysis of the ways the client could have done things differently. This is achieved by weighing up the pros and cons of alternative behaviours. The practitioner guides the client to articulate how they would do things differently in the future in order to stay HIV negative ('pros and cons',[b] 'problem-solving',[c,d] 'framing/reframing',[b] 'incompatible beliefs'[b]).
- Guide the client to articulate and commit to a specific action plan, persuade them about their capability and focus them on their identity as someone who used to take HIV infection risks but is now HIV negative ('action planning',[b–d] 'identity associated with changed behaviour',[b,c] and 'verbal persuasion about capability'[c,e]).

Structural elements (describing the overall intervention and its sequential elements)

Interventions should be associated with testing events.[f]

Interventions should be delivered face to face.[f]

Interventions should entail a reduction in negative affect and an increase in positive affect (steps 1–5).[c]

Interventions should be non-judgemental.[c]

Interventions should be multicomponent.[c,e]

Interventions should include a peer reference point (step 1).[c,e]

Interventions should have a risk assessment towards the beginning of their implementation (step 3).[c,e]

Interventions should be personalised (steps 2–5).[c,e]

Interventions should focus on intrasubjective elements (steps 3–4).[c,e]

Interventions should include a future-facing element (step 5).[c,e]

BOX 2 The evidence base that underpins the candidate intervention (*continued*)

Interventions should focus on a sense of personal responsibility throughout (steps 1–5).[c,e]

Interventions should demonstrate cultural competency with MSM (steps 1–5).[e]

a Expert opinion relating to increasing complexity of HIV risk (e.g. PrEP).
b Evidence from narrative synthesis of intervention components.
c Evidence from realist synthesis.
d Evidence from NICE regarding BCTs.
e Evidence from the content analysis focusing on patterns of potentially synergistic elements.
f Evidence from systematic review and exploratory meta-analysis.

EME
HS&DR
HTA
PGfAR
PHR

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